Import risk analysis: Belovo egg powders

REVIEW OF SUBMISSIONS

Biosecurity Authority
Ministry of Agriculture and Forestry
Wellington
New Zealand

5 September 2003

Ministry of Agriculture and Forestry
Te Manatu Ahuwhenua, Ngaherehere
ASB Bank House
101-103 The Terrace
P O Box 2526
Wellington
New Zealand

Telephone: +64 4 474 4100
Facsimile: +64 4 474 4133
Internet: http://www.maf.govt.nz

Animal Biosecurity
Biosecurity Authority

Import risk analysis: Belovo egg powders

Review of submissions

5 September 2003

Approved for general release

Derek Belton
Director Animal Biosecurity
Biosecurity Authority

TABLE OF CONTENTS

EXECUTIVE SUMMARY

Egg powders have been imported into New Zealand for many years. The countries for which import health standards exist reflect the requests that have been made to the Ministry of Agriculture and Forestry (MAF), and it has only been since the establishment of the Biosecurity Authority in 1998 that there has been a policy that new import health standards are to be based on risk analyses.

Requests to import three specific egg powders from a company based in Belgium (Belovo) were first received by MAF Biosecurity in the late 1990s, and in April 2003 MAF Biosecurity completed an import risk analysis on these products.

The risk analysis concluded that in view of the processing involved in their preparation (prolonged times at high temperatures), the egg powders did not pose a biosecurity risk, and that no safeguards were required.

The risk analysis was released for public consultation, and three submissions were received, from the New Zealand Food Safety Authority, the Department of Conservation, and the Poultry Industry Association of New Zealand.

Although one submission contended that high levels of a number of pathogens would be expected to be present in the egg powders defined in this risk analysis, the major concerns were in regard to certification of the time/temperature treatments used in processing. These matters are explained in MAF Biosecurity's responses in this document. Concern was also expressed that the egg powders could originate from a country other than Belgium. This matter will be addressed in the development of import health standards.

As a result of this review of submissions, MAF has concluded that no technical issues of significant biosecurity concern were omitted from the risk analysis on the specified Belovo egg powders. Therefore MAF's conclusion remains that the biosecurity risks associated with these products as defined in the risk analysis are negligible, and that import health standards for these commodities can be developed.

INTRODUCTION

1. BACKGROUND

While carrying out this analysis of submissions it became apparent that there was varied level of understanding among stakeholders of the reason that the risk analysis was undertaken by the Biosecurity Authority of the Ministry of Agriculture and Forestry (MAF).. Therefore it was considered useful to summarise the history of the Belovo egg powder risk analysis in this document.

Imports of egg powders into New Zealand

Egg powders have been imported into New Zealand for many years, and the issuing of import health standards (IHSs) for different countries has always been driven by import requests. Moreover, all of the current IHSs for egg powders predate the current policy that was developed following the formation of the Biosecurity Authority (MAF Biosecurity[1]) in 1998, of basing all new IHSs on risk analyses[2].

IHSs are currently in place for the following egg powders and countries:

Egg albumen powder	Australia Canada Denmark France Germany Italy The Netherlands Republic of Ireland Sweden United Kingdom United States of America
Whole egg powder & egg yolk powder	Australia Canada United States of America

The quantity of egg powders imported under these IHSs is considerable. MAFs import database shows that in the first seven months of 2003 about 40 tonnes of egg powders were imported, including 12,000 kg of egg albumen powder (EAP), from

[1] In this document, the abbreviation MAF will be used only in the context of the MAF Biosecurity Authority

[2] This is notwithstanding that the dates on the current egg powder IHSs are all post-January-1998. The date on an IHS is the date of last update, which is often a very minor change that does not require consultation, such as name changes for parts of MAF, changes to cross-referenced product standards, etc.

Canada, France, Germany and the USA, and 28,000 kg of whole egg powder (WEP) and egg yolk powder (EYP) from Australia, Canada and the USA.

A relatively small amount of egg powder is produced in New Zealand. According to the Poultry Industry Association of New Zealand (PIANZ), there is only one company manufacturing egg powders in this country, and the production for the year from April 2002 to March 2003 was about 5,600 kg of egg albumen powder, about 19,000 kg of whole egg powder and about 500 kg of egg yolk powder[3].

Thus, assuming that the imports over the first 7 months are indicative of the rest of the year, it appears that currently over a 12 month period almost 70 tonnes of egg powders is imported, while domestic production is about 25 tonnes. That is, almost three quarters of the total New Zealand consumption of egg powders is currently imported.

Egg product risk analyses

The initial request to import egg powders from the Belgian company, Belovo, was made in the late 1990s. In view of the above policy, it was clear that a risk analysis should be carried out on these products prior to including them in any existing IHSs. However, there was a range of outstanding requests to import eggs and other egg products at that time, and the Belovo egg powders were therefore included in the scope of MAF's intended risk analysis on "Hens' eggs for hatching and human consumption", which was initiated in early 2000.[4]

In the early stages of defining the scope of the hens' eggs risk analysis, it became clear that the Belovo egg powders were practically identical to those already being imported from other countries, and MAF considered that the highly processed nature of egg powders set this commodity apart from the many other commodities included in the rather broad scope of the intended risk analysis on hens' eggs.

A further development, in January 2001, was a meeting between MAF Biosecurity and counterparts from Agriculture Fisheries and Forestry Australia (AFFA), where it was decided that it would be appropriate for certain risk analyses to be carried out in cooperation with the Australian authorities and vice versa. From MAF's viewpoint, it was considered that where it appeared that a proposed importation was relatively non-contentious, such cooperation would be easier to justify to our stakeholders.

Therefore, in early 2001 MAF Biosecurity decided that it was not best use of scarce risk analyst resources to duplicate the work that AFFA had done and would do in the future on their risk analysis on "non-viable eggs and egg products" (NVEAEP). The AFFA Technical Issues Paper (TIP) for that risk analysis had been released for public comment in December 2000, and MAF considered it to be a useful starting point. At that time it was expected that the Australian authorities would complete the NVEAEP risk analysis sometime in 2001.

[3] Mike Brooks, Executive Director, Poultry Industry Association, email to H J Pharo dated 21 August 2003
[4] Biosecurity Issue 21, 8 August 2000.

Thus, in view of what MAF considered the relatively non-contentious nature of proposals to import NVEAEP, in April 2001 it was agreed among members of the project team (comprising MAF, the Department of Conservation and the Ministry of Health) that MAF should not proceed with its independent risk analysis on hens' eggs. Rather, it was decided that MAF should restrict its attention to hatching eggs, and when the AFFA risk analysis on egg products was complete, MAF would assess it, and would put together a supplementary document detailing any differences that MAF had with its scope or conclusions, and that these two documents would be released for public consultation in this country.

Progress with the AFFA risk analysis on NVEAEP was unfortunately slower than anticipated, primarily due to an unexpectedly high staff turnover rate in Biosecurity Australia. As a result, by late 2002 MAF Biosecurity came to the conclusion that what had appeared to be a relatively simple decision regarding Belovo egg powders, was being unreasonably delayed by these process issues.

Thus, in early 2003 MAF decided to proceed with a 'streamlined' risk analysis for Belovo egg powders. The justification for this was that the egg powders were considered to be a single, highly-processed commodity from a single country, which is consistent with the MAF policy on carrying out such an approach.[5] Although several other egg products were considered for a similar streamlined approach at the same time, none of them included relatively high time/temperature treatments that the egg powders did have, such that it was concluded that there was inadequate justification to remove them from the standard risk analysis approach.

The completed risk analysis on Belovo egg powders was released for public consultation on 16 April 2003. Public notification appeared in *Biosecurity*, issue 43, dated 1 May 2003, and submissions closed 6 weeks later on 16 June 2003.

An extension to the final closing date for submissions was granted to allow the Poultry Industry Association to complete their submission.

2. CONSULTATION

MAF received submissions from the following (in date order):

Name	Organisation Represented	Pages	Date Received
S MacDiarmid	NZ Food Safety Authority	1	14 April, 2003
J Perry	Department of Conservation	2	16 June 2003
M Brooks	Poultry Industry Association of New Zealand	63	20 June 2003

This document reviews each of the above submission in turn, mainly focusing on technical issues of contention.

[5] See Biosecurity 34, 15 March 2002.

The full text of the submissions from the New Zealand Food Safety Authority (NZFSA) and the Department of Conservation (DOC) are included in Appendix 1, but the length and format of the submission from the Poultry Industry Association of New Zealand (PIANZ) meant that it was not possible to include the entire submission in this appendix. Instead, only the 2 pages of the table of contents are included in Appendix 1. However, copies of the full PIANZ submission can be provided by MAF on request.

REVIEW OF SUBMISSIONS

1. INTRODUCTION

1.1 Submissions from DOC and PIANZ indicated that there was some confusion about the intended scope of the risk analysis.

MAF response: This risk analysis was to assess the potential risks associated with the importation only of the commodity as defined in section 2.2 i.e. egg powders produced using the specified pasteurisation of the final product (70 °C for 120 minutes for whole egg/egg yolk powder, or 64 ° C for 14 days for egg albumen). However, section 2.2 of the risk analysis shows that pasteurisation of the final product is not the only processing step involving temperature treatments. All processes involve an initial pasteurisation process of the liquid egg, a dehydration step, and then the spray drying process itself during which the egg material may reach a temperature as high as 170°Cs of prior to the final pasteurisation step imposed on the final product.

MAF chose to focus the risk analysis only on the final step for simplicity, that is, to determine whether it alone was adequate in terms of achieving a negligible risk, given that the agent was assumed to be present in the egg pulp prior to processing into powder. The alternative would be to consider in detail the additive risk-reduction effect of each processing step, which would increase the amount of analysis that was required, and which, if the final step were found to be adequate, would constitute unnecessary work.

1.2 DOC and PIANZ both expressed concerns regarding certification of egg powders and the need for assurances to be provided that the products imported into New Zealand comply with the commodity definition provided in the Risk Analysis.

- *MAF response:* Evidence of the appropriate certification relating to production and manufacturing standards applied by Belovo has been provided to MAF by the Belgian authorities, which is the competent veterinary authority in this case. The precise details of the required certification will be considered when developing the import health standard.

2. NEW ZEALAND FOOD SAFETY AUTHORITY

2.1 NZFSA commented that they had studied the risk analysis and were satisfied that microbiological food hazards have been adequately addressed. NZFSA supported the risk estimation and agreed that the biosecurity risks to the consumer posed by these products were negligible.

3. DEPARTMENT OF CONSERVATION

3.1 DOC indicates that more information on the hygiene requirements under EU directive 89/437/EEC should have been provided - in particular, details on methods used to minimise the risk of the raw egg material being contaminated pre processing. In addition, DOC considered that a hyperlink to Directive 89/437/EEC should be made available.

MAF response: MAF appreciates that stakeholders may find it difficult to locate EU legislation on the web. Directive 89/437/EEC can be downloaded from : http://europa.eu.int/eur-lex/en/search/search_lif.html
In the window "Search by Document Number, select 'Directive', Year '1989', and Number '437'.
Many sections of this directive cover methods to prevent contamination of raw egg material, and it is best read in its entirety.

3.2 While DOC considers that the list of diseases outlined in Section 3 is comprehensive, there is limited expertise within DOC in the area of avian pathology, so that DOC relies on staff in MAF Biosecurity to ensure that all possible pathogens associated with this product are considered.

MAF response: As stated in the hazard identification of the risk analysis the organisms considered in the MAF risk analysis on Belovo egg powders included those disease agents of poultry for which MAF considered transmission on or in eggs was possible: in eggs by virtue of the organism being recognised as being present in eggs; on eggs by virtue of the organism being known to be transmitted by faeces, in which case there is a theoretical possibility of contamination of egg shells.

The table on page 4 of the MAF risk analysis shows the justification for the decisions made in this regard, referenced to a standard textbook on poultry diseases (Calnek, 1997). In compiling this list, all known agents of poultry were considered, regardless of country of origin, the intention being to consider New Zealand's status only in regard to disease agents that the release assessment concluded were hazards on the basis of their ability to survive the time/temperature treatments of processing into egg powder.

A similar (albeit slightly shorter) list of potential hazards has been collated by the Australian authorities (AFFA), in the context of their import risk analysis on non-viable eggs and egg products, which is discussed in the introduction to this document. The AFFA list of hazards is part of the Technical Issues Paper for that risk analysis, dated December 2000, which is available on the AFFA website at: http://www.affa.gov.au/index.cfm.

As the table on page 4 of the MAF risk analysis on Belovo eggs considers organisms regardless of country of origin, it contains a number of disease agents that are not included in the AFFA hazard list.

However, the AFFA list includes the following four diseases that MAF did not consider to be potential hazards.

- Duck septicaemia (*Riemerella anatipestifer* infection). MAF did not include this disease in the list of potential hazards, as transmission is only by direct contact (through skin wounds of the feet or by the respiratory tract) — it is not transmitted in eggs, and attempts at transmission by oral inoculation have not been successful (Calnek, 1997, 162-163).

- Fowl cholera (*Pasteurella multocida* infection). MAF did not consider this as a potential hazard in this risk analysis, as it is transmitted in chickens by the respiratory route, and not via eggs or in faeces (Calnek, 1997, p 149).

- Infectious coryza (*Haemophilus paragallinarum*). MAF did not consider this delicate organism as a potential hazard, as transmission is by the respiratory route, and not via eggs or in faeces (Calnek, 1997, 180-182).

- Quail bronchitis (type 1 avian adenovirus). MAF did not consider this as a potential hazard in this risk analysis, as it is considered to be transmitted by the respiratory route (Calnek, 1997, p 621). However, faecal-oral and egg transmission has been documented for other avian adenoviruses, several of which are included in the MAF list of potential hazards.

3.3 DOC comments that, 'The hazard identification states that *"it is assumed that there is a low likelihood for agents that are transmissible on or in egg shells to be present in the pulp at the time of processing."* The assessment does not provide any evidence to support this assumption i.e. whether the eggs are washed before hand, or broken in such a way to ensure that there is little transfer of an external contaminant.'

MAF response: MAF's assumption of a low likelihood for this is based in part on the processing requirements contained in EEC Council Directive 89/437/EEC, in particular the requirements to clean and disinfect eggs prior to breaking, and to minimise contamination of egg pulp at breaking. However, regardless of the assumption of low likelihood of egg pulp, the agents listed in the hazard identification table on page 4 of the risk analysis are considered in the release assessment from the point of view of the likelihood of them being in the final product in view of the effect on them of the final pasteurisation time/temperature treatment described in the commodity definition (section 2.2).

3.4 DOC comments that '... the Risk assessment concentrates solely on the final pasteurisation process and whether or not any of the diseases identified in the hazard identification are able to remain viable after this treatment stage.'

MAF response: As discussed in response 1.1, MAF has indeed concentrated solely on the final pasteurisation step in the risk analysis. This was done deliberately in the expectation that stakeholders would understand that if that time/temperature were demonstrated to be adequate to inactivate a certain disease agent, then the other temperature steps (which are themselves not inconsiderable) would not need to be considered in the analysis.

3.5 DOC comments that 'The release assessment has assumed that the treatment temperatures will be maintained for the time periods stated and therefore the majority

of the diseases present in the hazard identification list will be destroyed during the manufacturing process.' DOC further comments that 'As no assessment of the risk has been undertaken in the event of a breakdown in these processes, the IHS should include some require an assurance from the company that the pasteurisation process has been adequately undertaken'.

MAF response: MAF considers that the requirements provided in Chapter II of the Annex of Council Directive 89/437/EEC adequately cover DOC's concerns in this regard. In particular, under point 5 of that text, the requirements for automatic temperature controls, a recording thermometer and a safety device. Further, Chapter VI of the Annex outlines the microbiological criteria that each batch of product must meet.

3.6 DOC comments that 'The IHS may need to stipulate treatment/post treatment testing and auditing procedures with an additional requirement that these are independently verified. Without this assurance, the risk analysis would then need to consider the risk of the other pathogens which had been ruled out due to the heat treatment…'

MAF response: As stated in Chapter VII of the Annex of Council Directive 89/437/EEC, establishments must be under the supervision of the competent veterinary authority to ensure that the manufacture of egg products meet the requirements of the directive. Thus, it is the responsibility of the Belgian Ministry of Agriculture to certify that Belovo egg powders comply with whatever measures are included in MAF's import health standard, including the commodity definition which defines the time/temperature treatments used in processing.

3.7 In regard to the release assessment conclusion in section 4.1.1 of the MAF risk analysis, DOC comments that 'This section again indicates that the only source of IBD virus would be faecal contamination of eggs shells. As commented earlier, some further information/reference to the low probability of this occurring should be included in the analysis before a final conclusion can be made.'

MAF response: Given the conclusion in the MAF risk analysis that the heat treatments stated in the commodity definition would result in negligible risk, the analysis that DOC requests is really not necessary. However, the requested information is given here for information.

The relevant aspects of the epidemiology of IBD are as follows:

- virus is transmitted by the faecal-oral route
- incubation period is 2-3 days
- the virus is present in the faeces of infected birds for up to 2 weeks post-infection.
- for infection to take place, birds must have a functional bursa of Fabricius, which means that infection is not commonly seen in birds under 3 weeks of age
- maximum susceptibility is between 3 and 6 weeks of age, corresponding to the period of maximum bursal development. In endemic situations, infection outside this age range would be unlikely.
- in unvaccinated flocks (these would be rare in endemic areas) it would be normal for all birds to very quickly become infected after introduction, as the virus is extremely contagious.

- in non-endemic situations, infection is possible if the virus is introduced up to about 16 weeks of age
- laying normally begins at around 20-24 weeks of age for meat breeders, and from 15-19 weeks for commercial layers.

Therefore, infection of layers is possible, but only in the situation where the virus is introduced into non-vaccinated flocks shortly before point of lay. This appears to have been the situation alluded to in the paper cited in the AFFA TIP that was cited in the PIANZ submission as evidence that infection of layers is possible.[6]

In light of the above facts, MAF considers that the likelihood of IBD virus being present in the faeces of layers in an endemic IBD situation is low. In such a situation, even if the virus were introduced into an unvaccinated flock shortly before point of lay, the likelihood of infection occurring in any birds is low (as most would have been exposed in early life), and the likelihood of spread would also be low. Therefore, MAF considers that the likelihood of faeces of layers containing IBD virus is low, and therefore the likelihood of IBD virus being on the surface of eggs is also low.

Further, MAF considers that the likelihood of virus being in egg pulp (after breaking) is negligible, as Council Directive 89/437/EEC requires cleaning and disinfection of eggs prior to breaking if they are dirty. Moreover, considering the dilution factors and the fact that virus would not grow in egg pulp (unlike bacteria), MAF considers that the amount of virus (titre) in egg pulp would be negligible.

3.8 DOC comments that: 'Overall the risk analysis conclusion is lacking in detail with regard to an assessment of effects on the environment and it is difficult to ascertain whether or not any assessment was in fact undertaken. There seems to have been no analysis as to the risk that these agents may pose to indigenous avian fauna.'

MAF response: In carrying out this risk analysis, MAF used the international standard animal health risk analysis procedure, which is detailed in OIE Standards and MAFs risk analysis handbook (Murray, 2002)[7]. As explained on page 43 of the handbook, and on page 26 of the 2003 OIE *International Animal Health Code*, a risk analysis can be concluded after the release assessment if it is concluded that the likelihood of potential hazards being released into New Zealand is negligible. This is in fact what was concluded on page 8 of the release assessment. Therefore there was no requirement to carry out exposure or consequence assessments, the latter of which being where the impact of hazards on indigenous flora and fauna is normally considered.

3.9 DOC questioned whether strains of chicken anaemia virus present in New Zealand might be of different levels of pathogenicity to those in Belgium.

MAF response: Although there are anecdotal reports of minor strain differences in pathogenicity of CAV isolates (e.g. Calnek, 1997, p 741) MAF's advice from Dr

[6] van den Berg TP, Gonze M, Meulemans G (1991). Acute infectious bursal disease in poultry: isolation and characterisation of a highly virulent strain. Avian Pathology 20: 133-43

[7] Murray N (2002) Import Risk Analysis- animals and animal products. MAF Biosecurity, Wellington

Erika Spackman of the USDA Southeast Poultry Laboratory in Athens Georgia USA, is that there little variation in pathotype among strains, and there is no clear and established system for categorising CAV as pathogenic or low/non-pathogenic. Many of the observations about variation of pathogenicity among strains apparently stem from experiments using concomitant infections with different immunosuppressive agents of chickens, which makes it difficult to objectively evaluate the effects of individual agents.

It appears to be generally accepted that all strains of CAV belong to one serotype (Calnek, 1997, p 741). A recent review article (Noteborn & Koch, 1995)[8] noted that DNA analyses from various isolated from across the world revealed only minor differences among isolates, and it was concluded that "Worldwide, the CAV genome is highly uniform, particularly in the coding regions and regulatory elements". In view of the above, MAF concludes that there is insufficient evidence to conclude that there are significant differences in pathogenicity of isolates of this virus between New Zealand and other countries.

It will be of interest to DOC that circoviruses are considered likely to be widespread in free living birds in New Zealand.[9]

3.10 DOC comments that: '…The risk estimation section states that "No safeguards are necessary". This statement should be expanded to state that "No additional safeguards other than the processing conditions outlined in Section 2.2 are required". Again the Risk Analysis is based on these processing procedures being effectively undertaken therefore, as stated above, the IHS will need to state these requirements and also that certification by the appropriate NPPO has been provided.'

MAF response: The processing conditions outlined in section 2.2 of the risk analysis are not safeguards arising from the risk analysis, but are rather part of the commodity definition. MAF is unaware of any certification role for a National Plant Protection Organisation (NPPO) in this context. Any certification will be provided by the Belgian competent veterinary authority, that is, the Belgian Ministry of Agriculture. That certification will include that the product complies with the definition of the commodities as stated in section 2.2 of the risk analysis.

[8] Noteborn MHM, Koch G (1995) Chicken anaemia virus infection: Molecular basis of pathogenicity. Avian Pathology 24: 11-31
[9] Twentyman CM, Alley MR, Meers J, Cooke MM, Duignan PJ (1999). Circovirus-like infection in a southern black-backed gull (*Larus dominicnaus*). Avian Pathology, 28, 513- 516

4. POULTRY INDUSTRY ASSOCIATION OF NEW ZEALAND (INC)[10]

4.1 In section 4.1.1 of the PIANZ submission, it is asserted that infection with IBD virus later than 20 weeks can be expected, that faecal contamination of eggs is likely, and that IBD virus will therefore be present in egg pulp.

MAF response: This point is similar to that raised by DOC, and this response is therefore similar to response 3.7

As pointed out in MAF's 1999 chicken meat risk analysis, the starting titre of virus in the particular product is of vital importance when considering the effect of temperature on virus inactivation in chicken products, as virus infectivity declines at a predictable rate at any given temperature. Therefore, when considering the likelihood of viable IBD virus being present in egg powder, it is first necessary to consider how the virus might get into the egg pulp prior to it being processed, and at what level it might be present in egg pulp.

As pointed out in the risk analysis, since IBD virus is transmitted by the faecal-oral route and is not transmitted *in* eggs, the only way that the virus could find its way into egg pulp would be by faecal contamination of eggs and by such contamination being transferred to the egg pulp during the process of egg breaking.

In order to assess the likelihood and degree of this happening, it is first necessary to be quite clear about the pathogenesis of IBD infection. When IBD virus is introduced into the gastrointestinal tract of chickens, it is picked up by gut macrophages and lymphoid cells as soon as 4 hours post infection, and these cells carry the virus to the bursa of Fabricius, via the portal blood. Within a few days of infection, high titres of IBD are found in various organs. Titres as high as 10^6 to 10^8 EID_{50} per g of tissue are found in bursa, spleen, thymus, liver of chickens that have died of IBD, and this is the result of the pronounced secondary viraemia that follows the massive replication of the virus in specific bursal lymphoid cells. However, since there is little replication in peripheral lymphocytes (mature cells), without that massive replication in the bursa, infection remains confined to small numbers of gut-associated cells, in which case there is negligible viraemia. In birds where there is less bursal involvement, the titre of virus in tissues is correspondingly less, and where there is no bursal involvement (e.g. in birds that do not have any residual bursal tissue), the titre of virus in tissues is considerably lower than the levels mentioned above. Thus, the level of virus in faeces depends on the degree of bursal involvement.

Thus, as pointed out in response to the DOC submission, MAF considers that the key epidemiological points relevant to the likelihood of IBD virus being present on eggs are as follows:

- incubation period is 2-3 days
- for infection to take place, birds must have a functional bursa of Fabricius — this means that infection is not commonly seen in birds under 3 weeks of age

[10] The PIANZ submission was made jointly by the Poultry Industry Association of New Zealand (Inc.) and the Egg Producers Federation of New Zealand (Inc.).

- maximum susceptibility is between 3 and 6 weeks of age, corresponding to the period of maximum bursal development, and in endemic situations, infection outside this age range would be unlikely.
- involution of the bursa begins at about 12 weeks and is usually complete by 20 weeks
- in unvaccinated flocks (which would be rare in endemic areas) it would be normal for all susceptible birds to very quickly become infected after introduction, as the virus is extremely contagious.
- in non-endemic situations, infection is possible if the virus were introduced into a flock up to about 16 weeks of age
- laying normally begins at around 20-24 weeks of age for meat breeders, and from 15-19 weeks for commercial layers.
- the virus is present in the faeces of infected birds for up to 2 weeks post-infection.

In light of the above facts, MAF considers that the likelihood of IBD virus being present in the faeces of layers in an endemic IBD situation is low. Even if the virus were introduced into an unvaccinated flock shortly before point of lay, the likelihood of infection occurring in any birds is low, as most birds would have been exposed in early life. For the same reasons, the likelihood of spread would also be low.

Nevertheless, although it might be somewhat unlikely, it is possible to imagine a scenario whereby IBD virus could be present in the faeces of laying hens. If the virus were introduced into a non-vaccinated flock, shortly before point of lay (or if a sufficiently different strain was introduced into a vaccinated flock such that it was not covered by the existing vaccination schedule), infection could occur in the few birds that had sufficient bursal tissue remaining. Following infection in these birds, the virus could be excreted in faeces for up to two weeks, so that in such flocks some birds could be laying eggs contaminated with faeces for perhaps the first 2 weeks of the laying period . This appears to have been the situation alluded to in the paper cited in the AFFA TIP, which was cited in the PIANZ submission as evidence that infection of layers is possible.[11]

However, there several reasons to suspect that the above scenario is of minor significance as far as egg pulp is concerned. Even if some layers in a flock were infected with IBD virus, considering the amount of virus likely to be in faeces of chickens that are laying eggs (considerably less than in tissues of acutely infected birds) and the amount of faeces likely to be present on eggs (even dirty eggs carry only milligrams of faeces), the amount of virus on the surface of any single egg laid by infected birds is likely to be low.

Further, since the EU directive requires dirty eggs to be washed (and disinfected, although this is targeted at bacteria likely to cause food poisoning, not IBD), the amount of virus present on the shells of eggs at the time of breaking is likely to be very low. And notwithstanding that some egg shell inevitably finds its was into the egg pulp during egg breaking, the provisions of Council Directive 89/437/EEC [Chapter V of the Annex] aim to minimise such contamination, and sampling has to be carried out to show that egg shell and membrane contamination does not exceed

[11] van den Berg TP, Gonze M, Meulemans G (1991). Acute infectious bursal disease in poultry: isolation and characterisation of a highly virulent strain. Avian Pathology 20: 133-43

100 mg/kg of the egg pulp [point 2(c) of Chapter VI of the Annex]. Therefore, only a small proportion of any virus on the shell would find its way into egg pulp.

Also, it must be remembered that since IBD is a virus, it means that, unlike the situation with bacterial contamination, it would not multiply in the egg pulp prior to further processing.

Finally, it is worth noting that there are important differences between the production processes for egg powders and those for chicken meat. While in egg powder production there is uniform mixing of the product, the focus for chicken meat remains on an individual carcass and the likelihood of it having been viraemic at slaughter. Thus, there are substantial dilution factors present in this situation (many thousands of eggs make up a single batch of egg pulp for processing into egg powder) that do not occur with chicken meat.

In view of the above factors, MAF considers that the amount of IBD virus (titre) in egg pulp would be negligible.

4.2 In section 4.1.1 of the PIANZ submission, it is suggested that the risk of IBD in egg powder was in some way influenced by the fact that "the Belovo egg powder comes from India and other undefined countries." The implication appeared to be that since the prevalence of IBD in India is high (a table was presented), the risk of egg powders was correspondingly high.

MAF response: MAF is not convinced that raw prevalence figures such as those for India provide a strong case for contending that the likelihood of IBD virus being present in egg pulp is significantly higher for some countries than for others. MAF considers that response 4.1 adequately covers the likelihood of IBD virus being present in egg pulp for any manufacturer of egg powder that conforms to or is equivalent to EU Council Directive 89/437/EEC, regardless of the country of origin of the egg powder or the raw egg ingredients. This issue is covered further in response 4.12.

4.3 In section 4.1.1 the PIANZ submission quoted an unidentified study commissioned by the Australian Quarantine and Inspection Service that indicated that chicken meat had to be cooked for 165 minutes at 74°C or for 125 minutes at 80°C to destroy IBD virus, and it was pointed out that these time/temperatures exceeded those used in the production of Belovo egg powder.

MAF response: PIANZ will be aware of the considerable work that MAF has undertaken in the past on modelling the heat inactivation of IBD virus, in particular in relation to the risk of the virus being present in cooked poultry meat.[12] It was on the basis of that work that MAF concluded in the Belovo egg powders risk analysis that 120 minutes at 70° C could be expected to reduce the titre of IBD virus by between 2 and 6 logs. MAF assumes that PIANZ is also aware that the requirements of the Australian authorities (AQIS) for chicken meat are not the same as their requirements for egg powders, and that in fact AQIS has permitted the importation of these egg powders into Australia for a number of years.

[12] See, in particular, Apendices 1 & 2 of the MAF Chicken Meat Risk Analysis dated March 1999. ISBN: 0-478-07987-7

As explained in MAF's 1999 chicken meat risk analysis, given that there is a constant decline of viable virus at any temperature above freezing, and that the rate of such decline depends on temperature, then the starting titre of virus in the commodity in question is of great significance. As can be seen from Appendix 2 of the MAF's 1999 chicken meat risk analysis, the starting titre for the inactivation curves in Figure 2 were based on an initial titre of $10^{5.17}$ CID_{50} per 0.1 ml of inoculum, which is an extremely high titre of virus. In response 3.1, it is explained why it is considered that if there is any IBD virus in egg pulp, it will be at a very low titre.

MAF has recently re-analysed[13] the data used in Appendix 2 of the 1999 chicken meat risk analysis to address what were initially thought to be "anomalies" in the results (see section 3 of that appendix for details). By applying a multiple regression model to the original data that was used to construct table 1 of that appendix[14], a predictive model has been developed that allows the number of logs decline in virus titre to be predicted for any combination of starting virus titre, temperature and time. Although the lack of data makes it difficult to predict with any confidence the effects of temperatures above 80°C, the model does enable the prediction of the effect of the final pasteurisation of egg powder at 70°C for 120 minutes. The model shows that the expected reduction of virus by such a treatment is about 4.5 logs. This remodelling of IBD inactivation by heating at various temperatures is included in Appendix 2 of this document.

In view of the amount of virus that may be assumed to be present in egg pulp, MAF considers that the 4.5 logs reduction that is achieved by the final pasteurisation of egg powder at 70°C for 120 minutes is adequate to deliver a negligible risk in the commodity.

4.4 PIANZ noted in section 4.2.1 of their submission that avian paramyxovirus type 1 (APMV-1) shows strain differences in sensitivity to heat and that there were various inactivation times reported in publications from 1957 to 1989. The submission cited a 1973 paper in claiming that APMV-1 virus was recovered from egg pasteurised by heating at 64.4°C for 200 seconds, and another study from 1991 that confirmed that simple pasteurisation was not adequate for inactivating the virus from egg, serum or diagnostic agents.

MAF response: It is difficult to understand what PIANZ is asserting here, as simple pasteurisation is clearly not the only heat treatment involved in the preparation of these egg powders, as shown in the commodity definition in section 2.2 of the risk analysis. While the raw material (yolk) for egg yolk powder is indeed pasteurised at 65.5°C for 3 minutes prior to dehydration, whole egg powder is submitted to that plus another aggressive heat treatment (60°C/36 minutes/300 bar) prior to dehydration. In both cases, dehydration is carried out at an inlet temperature of 145°C, and an outlet temperature of 60°C prior to spray drying, during which the material may reach 170°C. Finally, the finished product for these two egg powders are submitted to a long post-processing pasteurisation process in their final packaging, at **70°C for at least 120 minutes**. For egg albumen powder, there is no

[13] This work was carried out in July 2003 by AgResearch Biostatistician Neil Cox, in coordination with MAF Animal Biosecurity's National Manager Risk Analysis, Howard Pharo. It is included as Appendix 2 of this document.
[14] Australian Quarantine and Inspection Service, (1997) Report of the Scientific Working Group to Review the Weybridge Trials on Heat Inactivation of Infectious Bursal Disease (IBD) Virus. Department of Primary Industries and Energy. Canberra. Australia.

initial pasteurisation of the liquid albumen, but the final pasteurisation step involves holding for **14 days at not less than 64°C**.

PIANZ experts should be aware of MAF's work on the heat inactivation of Newcastle disease that was done as part of the 1999 chicken meat risk analysis. As explained in Appendix 3 of that risk analysis, in order to clarify the inactivation characteristics of this virus (which no doubt in part arose from the uncertainty remaining surrounding the results of the papers cited by PIANZ in this submission) the Commonwealth of Australia commissioned the Central Veterinary Laboratory in the UK (an OIE world reference laboratory for Newcastle disease) to investigate this matter in a systematic manner. The report from CVL to AQIS[15] was the basis for the modelling work carried out in Appendix 3 of the 1999 MAF chicken meat risk analysis, and MAF concluded that cooking chicken meat at 70°C for about 30 minutes was enough to reduce the titre from a starting level of 10^6 EID_{50}/g to a hypothetical target titre of about 10^{-8} EID_{50}/g.

It should be noted that the starting titre of 10^6 EID_{50}/g was the highest titre found in chicken heart/kidney/spleen following oral inoculation of 3-week old chickens with a highly pathogenic strain of APMV-1, and that it was necessary to use 10^4 EID_{50} to establish an infection in those chickens. For the same reasons that were discussed in relation to IBD, MAF considers that if there is any APMV-1 virus in egg pulp, it will be at a considerably lower titre than 10^6 EID_{50}/g, and that the likelihood of 10^4 EID_{50} of virus being in a chicken-edible volume of raw egg pulp is negligible.

Finally, as shown by the modelling of heat inactivation in Appendix 3 of MAF's 1999 chicken meat risk analysis, the final pasteurisation step of 70°C for 120 minutes can be expected to reduce the risk of Newcastle disease and other paramyxoviruses to a negligible level, regardless of the starting level in egg pulp.

4.5 At the end of section 4.2.1 of the PIANZ submission, it is concluded that "Exotic strains of NDV are a catastrophic threat to New Zealand's poultry industries, aviculture and the environment, which would impact on New Zealand's protected native fauna."

MAF response: MAF agrees with PIANZ that outbreaks of Newcastle disease in New Zealand poultry would have severe effects, particularly in flocks that have poor biosecurity (since spread is overwhelmingly by faeces and fomites contaminated by faeces). However, MAF does not believe that a persuasive case can be made in support predictions of dire consequences of Newcastle disease on the environment in general and native birds in particular.

Many strains of APMV-1 exist, and the consequences of introduction would depend on the characteristics of the particular strain introduced. In the last 5 years it has been demonstrated by the use of molecular techniques that there is a molecular basis to pathogenicity, and that virulent strains of APMV-1 emerge in poultry as a result of mutations in viruses of low virulence. Moreover, although it is likely that the vast majority of birds are susceptible to infection with APMV-1 strains of both high and low virulence for chickens, the disease seen with any given virus may vary

[15] Alexander D J (1997) Heat inactivation of Newcastle disease virus [NDV] in homogenised chicken meat. Contract No: FT0513 between the Commonwealth of Australia and the Veterinary Laboratories Agency. Central Veterinary Laboratory, United Kingdom.

enormously from one species to another. The clinical signs seen in birds infected with APMV-1 vary widely, and are dependent on factors such as: the virus, host species, age of host, infection with other organisms, environmental stress and immune status. It has not been determined whether there is something particular to poultry that allows or encourages non pathogenic strains of APMV-1 to mutate to virulence, or whether it is simply a matter of chance that happens due to the vast populations of birds that are commonly kept in commercial flocks. Although there have been a series of outbreaks of Newcastle disease in poultry flocks in New South Wales and Victoria since 1998, there has been no evidence of spread to Australian native birds from poultry flocks.

Since none of New Zealand's native birds are galliforms, and since native birds are mainly relatively solitary animals and certainly do not form flocks of thousands of individuals in the way that commercial poultry are kept, there are good reasons to believe that Newcastle is rather unlikely to affect native birds in this country even if there were to be an outbreak in commercial poultry flocks. However, in the absence of definite information to support such a conclusion, MAF recognises the need to adopt a precautionary approach. Nevertheless, in the case of the egg powders considered in this risk analysis, as is discussed in response 4.4, regardless of the likelihood of the virus being present in egg pulp, the risk posed by APMV-1 in egg powders is considered to be negligible.

4.6 With regard to avian influenza, PIANZ submitted in section 4.3 of their submission that avian influenza virus could not only be on or in the shell of eggs, it could also be present inside eggs. Several papers were cited in support of this.

MAF response: In the table on page 4 of the risk analysis, MAF considered that the risk of avian influenza was likely to be confined to the shell, either *on* or *in* the shell. Nevertheless, by including a "No?" in column 3 of that table, MAF was showing that it had been concluded that avian influenza virus transmission *in* eggs could not be discounted, although it was considered unlikely. In coming to that conclusion, MAF was accepting that there are theoretical reasons why there might be virus in eggs (e.g. as a result of viraemia), but MAF considered that there was not good evidence in the literature to show that this could definitely occur.

However, on page 13 of their submission, PIANZ cited a number of papers in support of their contention that avian influenza virus is likely to be *in* hens' eggs (as opposed to *on* or *in* the shell).

First, a DEFRA paper was cited to indicate that broken or contaminated eggs may carry the virus. MAF agrees with this, and considers this to be an example of *in* shell carriage of virus.

Second, PIANZ cited an article by Simon Shane in the World Poultry magazine. Note that the article as cited in the list of references could not be found by the MAF library (it apparently does not exist), but an article with the same title and same author was found in World Poultry Volume 19, No 3, 2003, p 16-17 (not volume 19, number 3, p 19). This article did not mention avian influenza, which is perhaps not surprising considering its title.

Third, PIANZ cited a 1980 paper by Moulthrop & Lanston regarding the consideration of vertical transmission in control programs. This clinical communication does not provide any evidence for vertical transmission, and in fact the word 'vertical' appears only in the abstract, where mention is made of the 'possibility of vertical transmission'. The nearest the paper comes to discussing this is the following statement: 'The possibility of a very low level of egg transmission cannot be entirely ruled out…'.

Fourth and fifth, PIANZ cited two papers in support of the statement that HPAI has been isolated from within eggs in natural (Cappucci et al, 1985) and experimental (Narayan et al, 1969) infections. MAF agrees that the Cappucci et al (1985) paper is evidence that the virus may be found *in* table eggs during natural outbreaks of HPAI, particularly in 'severely affected' layer flocks. The Narayan et al (1969) paper explains how, prior to dying within 10 days of artificial infection with a highly pathogenic virus, three eggs were laid from a group of 30 turkeys, and that the virus was isolated from the yolks of these three eggs. This also supports the PIANZ claim that in an outbreak of HPAI, some eggs that might carry the virus may be laid before the birds die, and MAF agrees that in the unlikely event that eggs were collected from flocks that were clinically affected with HPAI, some of the eggs would be expected to contain the virus.

However, regardless of whether the virus is present *on* or *in* eggs, MAF considers that the amount of virus likely to be present in egg pulp prior to processing is likely to be very low, for the same reasons as have been discussed in regard to IBD and APMV-1 in previous responses.

Moreover, as discussed in the release assessment of the risk analysis, considering that orthomyxoviruses are readily inactivated by heat, the time/temperature treatments involved in processing of egg pulp into egg powders will ensure that the risk of avian influenza virus being in egg powders is negligible.

4.7 At the conclusion of section 4.3, the PIANZ submission states: "The introduction of this virus [HPAI] would cause catastrophic effects on both the poultry industry and the protected native fauna."

MAF response: MAF agrees with PIANZ that the introduction of HPAI would have severe effects on the New Zealand poultry industry, particularly flocks that have poor biosecurity (since spread is overwhelmingly by faeces and fomites contaminated by faeces). However, MAF does not believe that a persuasive case can be made in support of the PIANZ statement regarding the likely effects of avian influenza on native birds. PIANZ experts should be aware that avian influenza is essentially pathogenic only in poultry[16], and that it is known to be carried asymptomatically by a wide range of waterfowl, waders and galliform birds in many parts of the world. PIANZ experts should also be aware that in the last 5 years it has been demonstrated by the use of molecular techniques that HPAI viruses appear not to exist in birds other than poultry. Rather, it is now widely recognised that LPAI H5 and H7 viruses that are commonly carried by wild birds (particularly waterfowl) become pathogenic only after being introduced into dense populations of poultry (particularly the

[16] Apart from one incident reported in Terns in South Africa in 1963, the only reports of disease in non-poultry species involve small numbers of starlings and sparrows found dead around infected poultry houses during outbreaks of HPAI.

extremely high density commercial flocks) and that the emergence of pathogenic strains involves a mutation of the haemagglutinin protein of the virus that allows it to grow in tissues outside the gastrointestinal and respiratory tracts. It has not been determined whether there is something particular to poultry that allows or encourages these mutations to occur, or whether it is simply a matter of chance that happens due to the vast populations of birds that are commonly kept in commercial flocks. Notwithstanding some speculation about the ability of passerines (sparrows and starlings) to become infected and to spread the virus between poultry farms, it has never been suggested that HPAI has been able to spread from infected poultry flocks to native birds during a number of HPAI outbreaks in Australia over the past 30 years.

Since none of New Zealand's native birds are galliforms, and since native birds are mainly relatively solitary animals and certainly do not form flocks of thousands of individuals in the way that commercial poultry are kept, and since HPAI has never been reported to spread from infected poultry flocks to native birds, there are good reasons to believe that HPAI is rather unlikely to affect native birds in this country even if there were to be an outbreak in commercial poultry flocks. Nevertheless, in the absence of definite information to support such a conclusion, MAF recognises the need to adopt a precautionary approach. But considering that orthomyxoviruses are readily inactivated by heat, as discussed in the release assessment of the risk analysis, the time/temperature treatments involved in processing of egg pulp into egg powders will ensure that the risk of avian influenza virus being in egg powders is negligible.

4.8 In section 4.4 of their submission, PIANZ commented that the introduction of exotic salmonellae such as *S. typhimurium* DT104 or *S. enteriditis* would have a significant impact on the New Zealand Poultry Industry and on public health. PIANZ also highlights the fact that the NZ Poultry Industry routinely monitors for the presence of *Salmonella* spp. to maintain the industry's low incidence.

MAF response: As stated in the risk analysis, MAF considers the risk of salmonellae in these egg powders to be negligible. Chapter VI of the Annex of Council Directive 89/437/EEC outlines the microbiological criteria that each batch of product must meet, and section 2.3 of the risk analysis shows that each batch has to be tested free of salmonella, and this would be certified by the competent veterinary authority which in this case would be the Belgian Ministry of Agriculture.

In its submission on this risk analysis the NZFSA considered that the risk analysis conclusions were appropriate. However, the NZFSA has further informed MAF Biosecurity that it reserves the right to intercept and test any food commodity for evidence of residues or human pathogens, and should violative residues or pathogens be detected, the NZFSA would place that product into an alert system and all imports would be tested until the problem no longer existed.

4.9 In section 4.5 of their submission PIANZ implied that the risk of Angara disease had been underestimated as a strain of the adenovirus causing this disease could survive for 18 hours at 56°C.

MAF response: Angara disease was included in the MAF's risk analysis, as can be seen in the hazard identification table on page 4. Although the PIANZ submission

did not make it particularly clear what the exact reference was for their claim, MAF is aware of the strain variability in heat resistance shown by group I adenoviruses. In addition to the OIE Review alluded to in the PIANZ submission, this subject is covered in Calnek (1997, p 611), where it is stated: *"Some strains survive 60 C and even 70 C for 30 min. One F1 virus fell rapidly in titre after 180 min at 56 C, while another F1 strain apparently survived 18 hr at 56 C."*
PIANZ experts should be aware that group I avian adenoviruses are considered commonplace in New Zealand[17], and that the majority of them have a limited role, if any, as primary pathogens[18]. Further, Angara disease is considered to be the result of infection with group I adenovirus serotype 4 or 8, although some workers consider that other factors are involved, and it is unclear from the literature how F1 virus relates to these serotypes. Moreover, the above text from Calnek implies that survival at 70°C for 30 minutes was uncommon, and that there was some doubt about the survival for 18 hours at 56°C.

As is stated in response 4.4, a number of heat treatments are involved in the preparation of these egg powders, as shown in the commodity definition in section 2.2 of the risk analysis. While the raw material (yolk) for egg yolk powder is pasteurised at 65.5°C for 3 minutes prior to dehydration, whole egg powder is submitted to that plus another aggressive heat treatment (60°C/36 minutes/300 bar) prior to dehydration. In both cases, dehydration is carried out at an inlet temperature of 145°C, and an outlet temperature of 60°C prior to spray drying, during which the material may reach 170°C. Finally, the finished product for these two egg powders are submitted to a long post-processing pasteurisation process in their final packaging, at **70°C for at least 120 minutes**. For egg albumen powder, there is no initial pasteurisation of the liquid albumen, but the final pasteurisation step involves holding for **14 days at not less than 64°C**. Therefore, MAF considers that the likelihood of heat-resistant group I adenoviruses being present in the commodities is very low.

4.10 In section 4.6 of the PIANZ submission, it is implied that MAF has understated the heat resistance of the avian reoviruses that cause viral arthritis, as they have been shown to survive for 8-10 hr at 60°C. PIANZ contends that internationally there are considerable differences in pathogenicity between strains of these viruses, although no reference was offered in support of this. Moreover, it is apparent from section 7 of the PIANZ submission that the PIANZ experts are under the impression that avian reoviruses are exotic to New Zealand.

MAF response: MAF is surprised that PIANZ experts are under the impression that avian reoviruses are exotic to New Zealand, as they have been isolated in this country for many years. Indeed, in the early 1990s they were considered to be so widespread that MAF developed an attenuated reovirus vaccine for use in the broiler industry to try to reduce leg deformities caused by arthritis.[19]

In view of the PIANZ concern about the possibility of reovirus surviving for 8-10 hours at 60 °C, MAF contacted a recognised international expert on avian reoviruses for advice.[20] MAF was advised that the cited paper described work that was carried

[17] Howell J (1992) Viral diseases and the New Zealand poultry industry. Surveillance 19(2), 15-17.
[18] See Calnek (1997) p 608
[19] Howell J (1992) Viral diseases and the New Zealand poultry industry. Surveillance 19(2), 15-17.
[20] Richard Jones, University of Liverpool, UK. email to H Pharo, 29 August 2003.

out in 1966, before the virus was identified, and the paper is not considered to be part of the mainstream literature on avian reovirus. Further, the expert considered unlikely that the paper would pass modern scrutiny, as although it reported virus survival of 6-8 hours, it was also explained that no virus was found at 6 hours, none was found at an unspecified intermediate time (7 hours?), and yet it was found at 8 hours. This expert considered that further work would be necessary to clarify this important discrepancy. Further, MAF was advised that although reovirus is egg transmitted, it is present in egg in very small amounts, erratically, and probably only in a proportion of the flock. This expert considered that if any virus were capable of surviving 70°C after 120 minutes, it would be a very small amount.

Concerning the likelihood of reoviruses to be present in egg powders, as is stated in response 4.4, a number of heat treatments are involved in the preparation of these egg powders, as shown in the commodity definition in section 2.2 of the risk analysis. While the raw material (yolk) for egg yolk powder is pasteurised at 65.5°C for 3 minutes prior to dehydration, whole egg powder is submitted to that plus another aggressive heat treatment (60°C/36 minutes/300 bar) prior to dehydration. In both cases, dehydration is carried out at an inlet temperature of 145°C, and an outlet temperature of 60°C prior to spray drying, during which the material may reach 170°C. Finally, the finished product for these two egg powders are submitted to a long post-processing pasteurisation process in their final packaging, at **70°C for at least 120 minutes**. For egg albumen powder, there is no initial pasteurisation of the liquid albumen, but the final pasteurisation step involves holding for **14 days at not less than 64°C**.

Thus, there is little basis for claiming that reoviruses would be likely to be present in egg albumen powder, and MAF considers that it is highly unlikely that viable virus would be present in any of these commodities.

Regarding the PIANZ claim that there is considerable variation in pathogenicity between strains, the reovirus expert referred to above commented that screening for pathogenicity can only be done by testing viruses in birds, as laboratory-based methods do not exist. While most reoviruses appear to be harmless, there are some that can be pathogenic, particularly for joints. However, the reoviruses already in New Zealand are known to cause joint problems in broiler flocks, and the lack of information on strain differences of the viruses here and abroad do not justify arguing that such differences warrant a precautionary approach in regard to these commodities.

4.11 In section 5 and 6 of their submission, PIANZ takes issue with MAF's suggested use of the imported commodities as stated in section 2.4 of the risk analysis.

MAF response: In hindsight, perhaps MAF should not have included section 2.4 of the risk analysis under the heading of "commodity definition", as it appears as if the intention is to restrict the imported powders to certain uses, whereas MAF's intention in section 2.4 of the risk analysis was to provide general information about end use of these products, rather than strict conditions controlling this. As PIANZ correctly points out, once an imported product is given a Biosecurity Clearance under the Biosecurity Act there is no way to restrict its final use. Nevertheless, considering that these egg powders are imported for processing into food for human

consumption, MAF considers that there is a very low likelihood that they will be used some of the purposes listed by PIANZ. However, as has been discussed in response 3.8, a risk analysis can be concluded after the release assessment if it is concluded that the likelihood of potential hazards being released into New Zealand is negligible. This is in fact what was concluded on page 8 of the release assessment. Therefore there was no requirement to carry out exposure or consequence assessments, the latter of which being where the impact of hazards on indigenous flora and fauna is normally considered

4.12 Section 8 of the PIANZ submission comprised four pages of general discussion on 'factors' relating to contamination of the commodities covered in the MAF risk analysis. Of particular concern to PIANZ is that "the eggs packaged under the Belovo brand name are likely to have been produced and processed in India and in other countries such as Russia, where Belovo has commercial connections."

MAF response: Although Council Directive 89/437/EEC is fully operational for EU member states, it does not apply to operations outside the EU as the proposed list of approved third country establishments has not yet been developed. Until that is done, bilateral arrangements that individual member states have with third countries shall continue to apply (see Article 11.1 of Directive 89/437/EEC). In this regard, it is theoretically possible for a company in an EU Member State to import either raw eggs or egg pulp for processing into egg powder, EU Decision 94/278 indicates that India is not one of the countries from which eggs can be imported. However, EU Decision 94/278 also shows that it is possible to import egg powders from India, and indeed Russia, and it would appear from the Belovo website that this has been done for many years. Further, it appears that these imported egg powders have been rebagged by Belovo and have been sold in the EU as Belovo products. This appears to have been the reason for the residue issue that prompted a recall of Belovo egg powders in early 2003.

MAF concluded in the risk analysis that the country of origin is not important with regard to biosecurity risks in these commodities. Provided the time/temperature treatments in section 2.2 are adhered to and the post-processing bacteriology requirements in section 2.3 are met, and this is certified by a competent veterinary authority recognised by MAF, the biosecurity risks associated with egg products are negligible.

Thus, the issues raised in sections 8.2 - 8.7 of the PIANZ submission are not of biosecurity concern, as the time/temperature parameters contained in section 2.2 of the MAF risk analysis and the measures in Directive 89/437/EEC are adequate to manage biosecurity risks. Similarly, section 8.8 of the PIANZ submission shows that PIANZ has failed to understand that the risk analysis based its conclusions primarily on the final pasteurisation step of processing. Thus, the spray drying temperature for WEP is not critical as long as the final pasteurisation step is at least 70°C for at least 120 minutes.

Nevertheless, MAF agrees with the concerns of PIANZ regarding the validity of certification of products from countries outside the EU for which MAF has not undertaken an assessment of the veterinary services. Therefore, MAF will ensure that

any IHS developed for these Belovo egg powders will include the requirement for the competent veterinary authority to certify that the eggs were laid in Belgium and that the egg powder was produced in Belgium in compliance with Directive 89/437/EEC.

4.13 Section 10 of the PIANZ submission consisted of the text of the original MAF risk analysis with PIANZ comments in bold. In Section11, PIANZ's "key points" are summarised.

MAF response: These two sections appear to be PIANZ working documents, where issues are identified and summarised. These issues have been dealt with individually in previous responses.

4.14 Section 12 of the PIANZ submission raised issues related to "quality of the egg product" in these commodities.

MAF response: In its submission on this risk analysis the NZFSA considered that the risk analysis conclusions were appropriate. Nevertheless, the NZFSA has further informed MAF Biosecurity that it reserves the right to intercept and test any food commodity for evidence of residues or human pathogens, and should violative residues or pathogens be detected, the NZFSA would place that product into an alert system and all imports would be tested until the problem no longer existed.

4.15 In section 14 of the PIANZ submission, it is claimed that the risk analysis does not conform to the MAF Biosecurity Policy Statement on Risk Analysis dated 9 February 2001, because:

- Clause 2.1 of the Policy Statement - this risk analysis may be in part a duplication of a similar risk analysis by the Australian Government, but if this is the case it has not been acknowledged by MAF, and in any case the conclusions differ to the Australian ones.
- Clauses 2.4 and 2.6 of the Policy Statement - this risk analysis does not consider the effects of pathogens on the environment
- Clause 2.9 of the Policy Statement - this risk analysis does not incorporate adequate precaution in the face of uncertainty arising from a lack of information.

PIANZ concludes in section 14.2 that the conclusions therefore are invalid and the risk analysis should be withdrawn.

MAF response: First, the MAF risk analysis is not in any way a duplication of an Australian Government risk analysis on this topic. Response 3.2 explains that the AFFA risk analysis on non-viable eggs and egg products that was hoped to be the basis for a similar MAF risk analysis has not progressed past the "technical issues paper" stage, primarily due to staffing issues at Biosecurity Australia. MAF considers that even if the hazard list for this risk analysis were identical to that of AFFA, it would not necessarily mean that one was the product of the other. However, the fact that the hazard list for this MAF risk analysis and the AFFA risk analysis are not the same demonstrates that somewhat different approaches taken. Further, since the AFFA risk analysis is not complete, there are no conclusions arising from it.

Moreover, the fact that Belovo egg powders have been imported into Australia for many years suggests that it is highly unlikely that the conclusions of the AFFA risk analysis, when it is complete, will differ from those in this MAF risk analysis. However, it would by no means be impossible for them to differ even if exactly the same scientific literature were used in assessing the risk, because it is quite normal under the WTO SPS agreement for different countries to adopt different levels of protection. This means that it is certainly possible for different safeguards to be adopted by different countries even if their risk assessments were very similar.

Second, the MAF Biosecurity Policy Statement referred to[21] makes it clear in section 1.5 that import risk analyses will be developed under the Biosecurity Act 1993, taking into account of a number of related documents. Key in this regard is the OIE International Animal Health Code, which contains (in section 1.3) guidelines for risk analyses on animals and animal products. The need to consider these standards is also made clear in Section 22(5)(c) of the Biosecurity Act 1993. As explained in response 3.8, in carrying out this risk analysis, MAF used the international standard animal health risk analysis procedure, which is detailed in both the OIE *International Animal Health Code* and in MAFs risk analysis handbook that was published in January 2002, which is why the latter is not reflected in the 2001 Policy Statement. As explained on page 26 of the 2003 OIE *International Animal Health Code*, and on page 43 of the MAF handbook, a risk analysis can be concluded after the release assessment if it is concluded that the likelihood of potential hazards being released into New Zealand is negligible. On page 8 of the MAF risk analysis on Belovo egg powders it was in fact concluded that the likelihood of release of agents of biosecurity concern was negligible in the commodities as defined in section 2.2 of the risk analysis. Therefore there was no requirement to carry out exposure or consequence assessments, the latter which being where the impact of hazards on the environment is considered.

Third, the MAF Policy Statement makes it clear that complete certainty is impossible in any biological system, as uncertainty results from both variability and lack of information. The MAF Policy Statement makes it clear that this needs to be decided on a case-by case basis, and in this risk analysis MAF has concluded that the degree of uncertainty is not of sufficient magnitude to warrant imposing safeguards as a precautionary approach.

4.15 Appendix C of the PIANZ submission consisted of a legal opinion provided by MinterEllisonRuddWatts (MERW), dated 4 June 2003 on the product coverage and application to third countries on EU Council Directive 89/437/EEC, and an overview of the Belgian company Belovo.

MAF response: MAF considers that MERW to be generally a correct analysis of the EU legislation. However, the MERW opinion appears to have overlooked the point discussed in response 4.12 regarding the possibility for EU Member States to import egg powder from India under EU Decision 94/278, and the apparent ability to rebag and relabel this as being a Belovo product. Therefore, the point made in section 4.16 of the MERW opinion appears at odds with the conclusion made in the summary under section 2.1 (c). Nevertheless, as indicated in response 4.12, MAF will ensure

[21] See Biosecurity Issue 26, 15 March 2001, p 7-10.

that any IHS issued for Belovo egg powders excludes the possibility that they were in fact produced in a third country.

MAF does not necessarily agree with the final sentence that appears in brackets in section 6.2 (c) of the MERW opinion. MAF is unaware of any particular experience or expertise that MERW has in animal biosecurity risk analysis that would justify their opinion that "*it is likely that a different range of pests and diseases associated with egg products would require consideration in any risk analysis that included India/New Zealand as a pathway*." Rather, MAF considers that, provided the egg powders are adequately verified as conforming to the commodity definition in section 2 of the Belovo egg powder risk analysis with regard to time/temperature parameters, post-production testing, and standards equivalent to Directive 89/437/EEC, the biosecurity risks would be negligible regardless of the country of origin. This is because all known pests and diseases associated with eggs have already been considered in the release assessment of the MAF risk analysis. As stated in response 4.12, the issue is one of confidence in the ability of the competent veterinary authority to certify to MAF's satisfaction, rather than any lack of confidence in the safety of the commodities that have been properly processes as indicated.

CONCLUSION

Egg powder has been imported into New Zealand for many years from 11 countries on three continents, and imports currently comprise almost 75% of the total consumption of egg powder in this country.

MAF is not aware of any report in the scientific literature to suggest that international trade in egg powders has ever been considered to be responsible for the introduction of avian pathogens into any country.

This risk analysis examined the risks associated with three specific egg powders from a Belgian company, Belovo. The commodities in question were defined in terms of the time/temperature processes involved in their manufacture, and the testing parameters with which they must conform under the relevant EU legislation. While these products are very similar to those already imported from a number of European Union member states, as well as from North America and Australia, their production involves a pasteurisation step of the final product that is not included in the definitions of the other powders, which means they are at least as safe as the egg powders that are currently imported into this country. In view of this similarity, and in view of their highly processed nature, MAF carried out a streamlined risk analysis for these commodities in accordance with MAF policy.

The risk analysis began by assembling a list of all currently known poultry disease agents that are recognised as potentially able to be transmitted in or on eggs. Therefore, the release assessment addressed the following question : 'if the agents were present in or on eggs, what would be the likelihood of them being present in the final processed product'? In other words, the focus of the risk analysis was on the specific commodities considered in the commodity definition, and the risk analysis was a consideration of the risks, given that definition.

The risk analysis concluded that the likelihood of significant amounts of any of the agents considered being present in egg powders that conformed to the commodity definition was negligible. Thus, the risk associated with these commodities was assessed as negligible, and therefore safeguards were not required.

No technical issues were identified in submissions to give MAF reason to alter the conclusion of the risk analysis. However, two submissions questioned the confidence that MAF could have in certification issued by the competent authority in Belgium, a matter that will be considered during the development of import health standards. In particular, a loophole in EU legislation was identified that allows egg powders to be imported into the EU from third countries and to be re-bagged and re-labelled as product of EU origin, and import health standards will ensure that product imported into this country originates in the country of the certifying authority. Notwithstanding this situation, a legal opinion provided by one stakeholder group on the legislation under which egg powders are produced in the EU raised no substantial issues. A challenge by one stakeholder group to the validity of the MAF risk analysis on the grounds that it did not follow stated MAF policy is considered by MAF to be unfounded.

In view of the approach taken in this risk analysis, that is, to consider all currently known poultry disease agents that are recognised as potentially able to be transmitted in or on eggs, irrespective of country of origin, the conclusions reached in this risk analysis will clearly have a strong influence on future import requests for powders conforming to the commodity definition used in this risk analysis.

However, as is explained in the introduction to this document, a broader egg product risk analysis that is currently underway by Biosecurity Australia is expected to become the basis of a more comprehensive analysis of a wider range of egg products by MAF when completed.

APPENDIX 1: COPIES OF SUBMISSIONS

1. NEW ZEALAND FOOD SAFETY AUTHORITY

From: Stuart MacDiarmid
To: Pharo, Howard
Date: 14/04/2003 15:45:24
Subject: Import risk analysis: Belovo egg powders

Howard,

Thank you for giving the New Zealand Food Safety Authority the opportunity to comment on the import risk analysis: Belovo egg powders.

My colleagues and I have studied the risk analysis and are satisfied that microbiological food hazards have been adequately addressed. We support the risk estimation and agree that the biosecurity risks to the consumer posed by these products are negligible.

Yours sincerely,

Stuart C MacDiarmid
Principal Adviser, Zoonoses and Animal Health,
Programme Development Group,
and Adjunct Professor in Veterinary Biosecurity (Massey University)

New Zealand Food Safety Authority
PO Box 2835
South Tower, 86 Jervois Quay
Wellington
New Zealand

Phone: +64-4-463 2500
DDI: +64-4-463 2648
Fax: +64-4-463 2530
Mobile: 021 443 501

2. DEPARTMENT OF CONSERVATION

Import Risk analysis: Belova Egg Powders

Thank you for providing the Department of Conservation with this Import Risk Analysis for review. The Department would like to make the following comments;

Processing

The executive summary and the description of the commodity indicates that the product is made by a Belgium company (Belova) working according to GMP rules on hygiene and health problems affecting the production and the placing on the market of egg products (89/437/EEC).

A brief description of the hygiene requirements pre processing would have been useful background information in the risk analysis providing details on the methods used to minimise the risk of raw egg material being contaminated pre processing. It would also have been useful to include a hyperlink to these rules either in the document or as an addition to the reference list provided.

Hazard Identification

The list provided in this analysis appears to be comprehensive. The Department has very limited expertise in the area of avian pathology and therefore would rely on MAF Biosecurity ensuring that all possible pathogens associated with this product are considered.

The hazard identification states that *"it is assumed that there is a low likelihood for agents that are transmissible on or in egg shells to be present in the pulp at the time of processing."* The assessment does not provided any evidence to support this assumption i.e. whether the eggs are washed before hand, or broken is such a way to ensure that there is little transfer of an external contaminant. Reference to company working according to GMP rules implies that this may be the case, but more implicit information should be provided to support this assumption. As indicated earlier a brief discussion on the pre processing practices would be useful.

Risk Assessment

The Department notes that the Risk assessment concentrates solely on the final pasteurisation process and whether or not any of the diseases identified in the hazard identification are able to remain viable after this treatment stage. The release assessment has assumed that the treatment temperatures will be maintained for the time periods stated and therefore the majority of the diseases present in the hazard identification list will be destroyed during the manufacturing process. The Department notes that in all three production processes, high temperatures (i.e. above 64-70 degrees Celsius) and considerable time (minimum 120 minutes- up to 14 days) are required in the final stage in order to pasteurise the powdered products. As no assessment of the risk has been undertaken in the event of a breakdown in these processes, the IHS should include some require an assurance from the company that the pasteurisation process has been adequately undertaken. The IHS may need to stipulate treatment/post treatment testing and auditing procedures with an additional

requirement that these are independently verified. Without this assurance, the risk analysis would then need to consider the risk of the other pathogens which had been ruled out due to the heat treatment.

The present risk analysis conclusion indicates that there are only three agents that may potentially withstand the final treatment process i.e. the IBD virus, chicken anaemia virus and the parvoviruses causing Derzsy's disease of geese and disease in young muscovy ducklings. This section again indicates that the only source of IBD virus would be faecal contamination of eggs shells. As commented earlier, some further information/reference to the low probability of this occurring should be included in the analysis before a final conclusion can be made.

Overall the risk analysis conclusion is lacking in detail with regard to an assessment of effects on the environment and it is difficult to ascertain whether or not any assessment was in fact undertaken. There seems to have been no analysis as to the risk that these agents may pose to indigenous avian fauna. For example:

- the analysis indicates that the chicken anaemia virus is already present in New Zealand, however there has been no discussion of whether or not the strains present in Belgium are of greater pathogenicity then those endemic to New Zealand. Has any work been undertaken overseas with regard to different levels of pathogenicity?

Risk estimation

The risk estimation section states that "No safeguards are necessary". This statement should be expanded to state that "No additional safeguards other than the processing conditions outline in section 2.2 are required". Again the risk analysis is based on these processing procedures being effectively undertaken , therefore as stated above, the IHS will need to state these requirements and also that certification by the appropriate NPPO has been provided.

3. POULTRY INDUSTRY ASSOCIATION OF NEW ZEALAND (INC)

Contents Page

APPENDIX 2: MODELLING OF IBD INACTIVATION

This is a comment on the data, analysis and interpretation presented in the MAF report (Import risk analysis: chicken meat and chicken meat products; Bernard Matthews Foods Ltd turkey meat preparations from the United Kingdom) in Appendix 2.

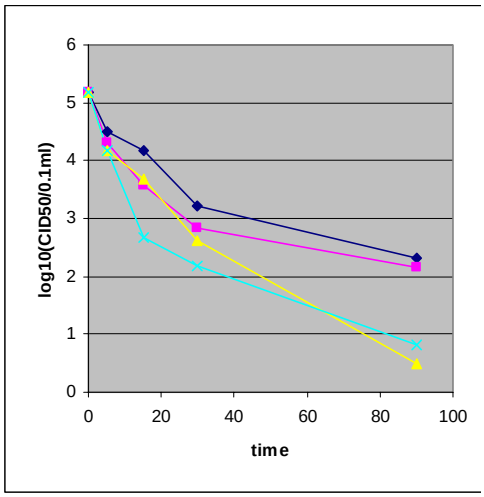
Neil Cox
Senior Statistician
AgResearch, Ruakura
14 July 2003

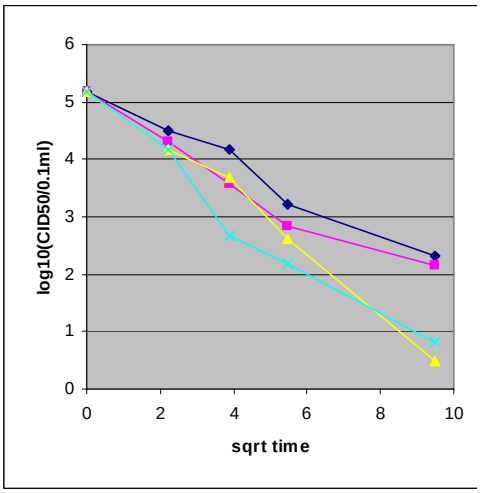
Data from Original CVL study (CVLS/06/97)

Temperature (°C)	**Virus titre (log_{10} CID_{50})**	**Time (minutes)**
60	5.17	0
60	4.5	5
60	4.16	15
60	3.22	30
60	2.32	90
70	5.17	0
70	4.32	5
70	3.57	15
70	2.83	30
70	2.16	90
74	5.17	0
74	4.17	5
74	3.68	15
74	2.63	30
74	0.5	90
80	5.17	0
80	4.16	5
80	2.68	15
80	2.17	30
80	0.83	90

Note that in the analysis done by Best and Brown in the 1997 Australian report (Report of the Scientific Working Group to Review the Weybridge Trials on Heat Inactivation of Infectious Bursal Disease (IBD) Virus), the last data point is omitted but I can find no discussion of why. I note, however, that this value and the 2nd last

value are shown as <0.83 and <2.17 in the original study report (Heat inactivation of infectious bursal disease virus strain CS88, CVLS/06/97).





Modelling relationship between logCID and time

Clearly from the graphs, the relationship between $\log CID_{50}$ and time is not linear but that between $\log CID_{50}$ and sqrt(time) is approximately linear. In fact, a model that sets the intercept at the known value of 5.17 and allows the slope to vary with temperature looks the right model to fit.

Note that in the MAF report (Import risk analysis: chicken meat and chicken meat products; Bernard Matthews Foods Ltd turkey meat preparations from the United Kingdom) in Appendix 2, the graphs (Figure 2) show this model being fitted, but the estimates shown in Table 3 are derived by fitting a model that allows the intercepts to vary, rather than being all fixed at 5.17. This difference looks to be of little consequence from the model fitting point of view but it does lead to unfortunate estimates in Table 3 where the estimate of the time required at 80°C is longer than at 74°C. The model that fixes the intercept produces more consistent estimates.

The table below shows the fitted line slopes and the times for 6D reduction for the 3 models fitted (as done in the MAF report, the same as Best & Brown but with all data, the same as Best and Brown with the last point omitted).

	indep. lines	fixed intercept	fixed interc (80° 90min omitted)	
temp	**Slope of fitted line (logCID v sqrt(time))**			
60	-0.309	-0.3081	-0.308	
70	-0.3242	-0.3534	-0.353	
74	-0.4951	-0.4731	-0.473	
80	-0.4654	-0.4965	-0.567	
	Time from start to 6D reduction			
60	377.0	379.2	379.5	
70	342.5	288.3	288.9	
74	146.9	160.8	160.9	
80	166.2	146.0	112.0	

Note that by fitting a model that is linear in sqrt(time) rather than time, we lose the nice property that a fixed reduction in $\log CID_{50}$ (eg a 6 reduction) takes the same length of time throughout the cooking time; but the reality is that the data shows that the time taken for a 6 reduction increases through cooking time. Hence, in the table above I have shown the time taken from the start to get a 6 reduction in $\log CID_{50}$.

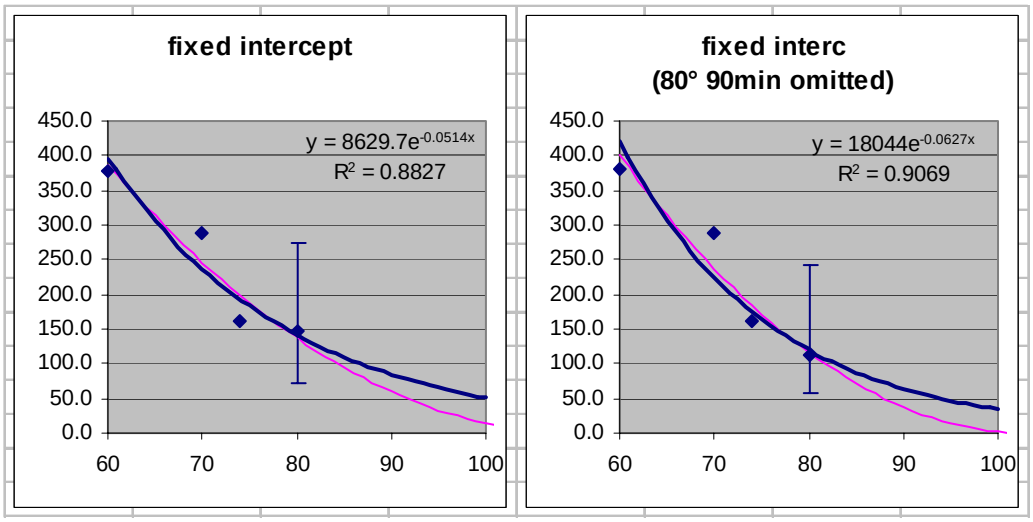
Because it is a simpler model and because it leads to more consistent estimates, I suggest we use the Best and Brown model.

Modelling the relationship between the times to 6D reduction and temperature

Best and Brown chose to model the relationship between the temperatures and the slopes from the $\log CID_{50}$ against time models with an inverse linear model; this model looks adequate (given only 4 points, determination of the "right" model is difficult). That leads to a quadratic model for the relationship between temperature and time to 6D reduction. I previously used an exponential model for the latter relationship. Within the data, the alternative models are essentially the same but for two reasons I prefer the exponential model for extrapolation; the reasons are:

- It gives slightly more conservative (longer) estimates.
- It behaves more sensibly (the Best and Brown model gives a zero time at about 100°C, then increasing times beyond that; of course extrapolation this far out is very risky but I prefer to fit a model that does behave more realistically when extrapolated).

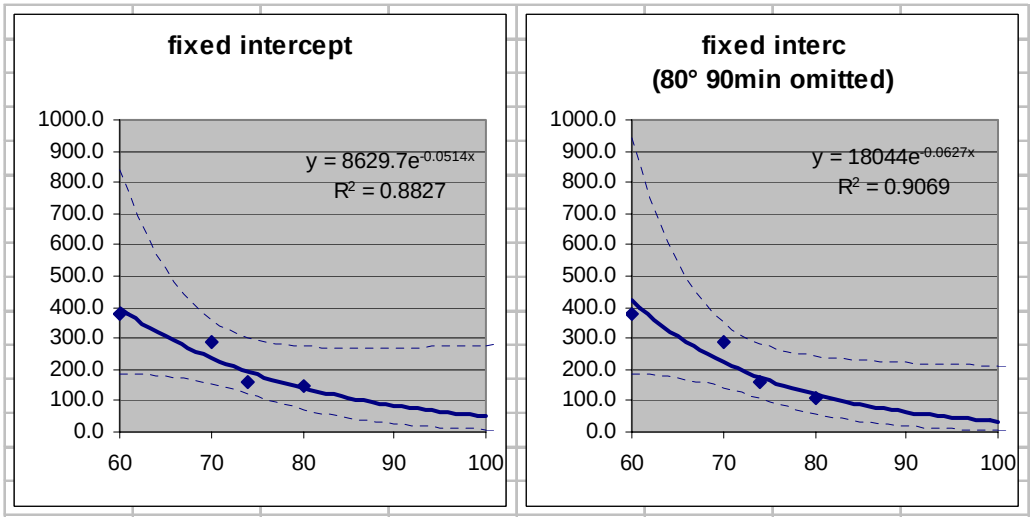
The following graphs show both models; the exponential model is the heavier blue line and the Best and Brown model is the thinner purple line. (The error bar the shows the prediction 95% confidence interval from the exponential model at 80°C.)



The whole model can be fitted in one stage, rather than in the 2 steps as has been done above.

Prediction of time required at various temperatures

The graphs below show the exponential model with upper and lower 95% confidence limits. We can see that the model with the last point omitted gives slightly better predictions at higher temperatures. The upper 95% confidence limit for temperatures beyond 80°C up to 100°C is essentially constant, so without more data, we would have to use the upper confidence limit at 80°C (274mins using all data, 243mins omitting one point) as the time we can be confident is sufficient for 6D reduction at temperatures from 80°C and above.



Predicting $logCID_{50}$

The whole model can be fitted in one stage, rather than in the 2 steps as has been done above. We modelled the time required to reduce $logCID_{50}$ by 6 by

$$T6D = a*\exp(-b*Temp°C),$$

where a and b are the parameters to be estimated from the data.
$logCID_{50}$ at time t is estimated as

$$logCID_{50} \text{ at start} - \text{sqrt}(t)*6/\text{sqrt}(T6D)$$

Combining these 2 formulae, we get

$$logCID_{50} \text{ at time t} = logCID_{50} \text{ at start} - \text{sqrt}(t)*\exp(b*Temp°C)/(\text{sqrt}(a)/6).$$

We can re-write this as

$$logCID_{50} \text{ at time t} - logCID_{50} \text{ at start} = A*\text{sqrt}(t)*\exp(b*Temp°C)$$

or

$$\text{Drop in } logCID_{50} = logCID_{50} \text{ at time t} - logCID_{50} \text{ at start} = A*\text{sqrt}(t)*\exp(b*Temp°C)$$

or

$$\log(\text{Drop in } logCID_{50}) = \log(A) + 0.5*\log(t) + b*Temp°C.$$

If we let the 0.5 coefficient become a parameter (ie don't force the sqrt transformation on time), this is a simple multiple regression of the log of the drop in $logCID_{50}$ against log(time) and temperature. In fact, what I have fitted is is the log of the drop against the deviations from the mean of log(time) and temperature; this makes the estimated coefficients independent of each other and simplifies calculation of confidence intervals of predictions.

The multiple regression model parameters are:

	estimate	se
Constant	0.6216	0.0328
temp	0.02734	0.0045
logtime	0.5016	0.0312

Note that the coefficient for log(time) is very close to the value of 0.5 used in the 2-stage process.

The predictive model is thus

$$\log(\text{Drop in } logCID_{50}) = 0.6216 + 0.5016*(\log(t) - 3.0546) + 0.02734*(Temp°C - 71).$$

(all logs are natural logs: ie base e)

Adequacy of Data

Best and Brown noted the large drop in estimated time between 70°C and 74°C and suggested more data in here would be useful. They also cautioned against extrapolating beyond 80°C. I agree with these conclusions. The upper confidence limit for the time required for temperatures above 80°C is essentially the same as that at 80°C, showing that, in the absence of data at higher temperatures, we must stay with the time required at 80°C for any temperature beyond this.

Hence we cannot be sure, from the data we have, that any time under about 4 hours is sufficient to reduce the $logCID_{50}$ by 6 at any temperature from about 80°C up.