# Development of the import health standards for pig meat and pig meat products

# **Summary**

New Zealand has a relatively small pork industry, with around 300 commercial producers supplying the domestic market. Exports are negligible. Production has remained largely static for the past decade while consumption has steadily increased. As a result, over 40% of the pork meat (including bacon and ham) consumed in New Zealand is imported. Major suppliers are Australia, Canada, the United States and Europe.

Import health standards for imports of pig meat and pig meat products have been in place for decades. The Ministry for Primary Industry's (MPI's) role under the Biosecurity Act in developing these standards is to effectively manage the risk of diseases establishing in New Zealand, while meeting our obligations under international agreements for science-based and least-trade-restrictive import requirements.

In 2001 unpublished research indicated Porcine Reproductive and Respiratory Syndrome (PRRS) could be transmitted to healthy pigs by feeding them fresh meat from recently-slaughtered PRRS-infected pigs. This led MPI to restrict pork imports from countries where PRRS is present to meat that had been cooked or cured, processes which inactivate the virus that causes PRRS.

Since then, MPI spent the best part of 10 years assessing the available science on PRRS, carrying out a biosecurity risk assessment of raw pig meat, and consulting stakeholders before deciding whether to permit the resumption of imports of raw pig meat.

In April 2011 MPI's Director-General issued new requirements relating to raw pig meat in four Import Heath Standards for pig meat, pig meat products and by-products from Canada, the EU, Mexico and the USA – all countries where PRRS is present. The standards restrict imports of raw pig meat to consumer-ready cuts weighing no more than 3kg, with lymph nodes removed, derived from healthy pigs that have been subject to ante and post-mortem inspection and certified for human consumption by official veterinarians in overseas countries.

The New Zealand Pork Industry Board, NZPork, applied to the High Court for judicial review of statutory decisions related to the issue of the new import health standards. This was granted in May 2011 and the substantive hearing was held in August 2011. On 3 May 2012 the Court ruled in favour of MPI.

In May 2012, NZPork appealed the High Court decision to the Court of Appeal. The High Court granted further interim orders in June 2012, staying the introduction of those parts of the new import health standards that relate to imports of 'consumer ready cuts' of raw pork from countries where PRRS is present.

NZPork's appeal was heard in the Court of Appeal on 28 November 2012. Interim relief orders were extended until 14 days after the Court of Appeal issues judgement on the appeal. On 18 March 2013, the Court of Appeal dismissed NZPork's appeal.

In April 2013 the NZ Pork Board applied to the Supreme Court for leave to appeal the Court of Appeal decision.

On 15 May 2013 the Supreme Court granted the application to appeal the Court of Appeal decision."

On 26 June the appeal was heard in the Supreme Court. The Court allowed the National Beekeepers Association (NBA) to intervene on the basis that the matters on which the NBA wished to make its submission were considered to be potentially helpful to the Court.

On 20 December 2013, the Supreme Court delivered its judgment, dismissing NZPork's appeal by a majority decision. The effect of this judgment is that interim relief has now lapsed.

# Timeline

Aug-2001	New Zealand imposed provisional measures restricting the import of uncooked pork from countries where PRRS is present. This followed research showing that the PRRS virus could be transmitted to pigs by feeding them pig meat taken from animals infected with PRRS under experimental conditions
Late 2005	MPI completed draft of Import Risk Analysis on pig meat and pig meat products, and sent it to international experts for peer review
Jun-06	MPI released the Import Risk Analysis for public consultation.
Jul-07	MPI released a Review of Submissions on Import Risk Analysis
Nov-07	MPI released draft pork Import Health Standards based on the Import Risk Analysis released for public consultation.
Mar-09	MPI released a review of Submissions on draft Import Health Standards
Apr-09	MPI issued provisional Import Health Standards for pig meat from the European Union, Canada, USA and Sonora State of Mexico.
May-09	NZPork requested a review of the provisional Standards, under section 22A of the Biosecurity Act 2003.
Aug-09	Director-General of MPI agreed to the appointment of an independent review panel under the process specified in s22A of Biosecurity Act.
Oct-09	Members of the independent review panel confirmed. The panel was made up of three technical experts from Europe and the US, with a senior New Zealand lawyer as chair.
31-Mar-10	Independent review panel provided report to Director-General. The report made 29 recommendations, covering a variety of technical and process-related issues.
30-Aug-10	Chief Technical Officer provided advice to Director-General on how to respond to Independent Review Panel advice. MPI carried out further analysis, including quantitative modelling.
Sept-Oct 2010	Expert Working Group reviewed MPI quantitative modelling carried out in response to Panel advice. Expert Group reported back on 7 November.
Dec-10	MPI Chief Technical Officer briefed Director-General on findings of Expert group.

Apr-11	MPI issued new Import Health Standards
May-11	NZPork sought judicial review of MPI decision at High Court in Wellington. Judge granted interim relief to prevent trade until hearing scheduled for August 2011
May-12	High Court ruled in favour of MPI's decision to allow the importation of raw uncooked pork from countries where the disease Porcine Reproductive and Respiratory Syndrome (PRRS) is present.
May-12	NZPork appealed the High Court decision to the Court of Appeal. Interim orders staying the introduction of the new import health standards are in place until the hearing.
Nov-12	NZPork's appeal was heard by the Court of Appeal.
Mar-13	The Court of Appeal dismissed NZ Pork's appeal.
Apr-13	The NZ Pork Board applied to the Supreme Court for leave to appeal the Court of Appeal decision
May-13	Leave to appeal was granted
May-13	On 31st May 2013 the Supreme Court granted further interim relief pending determination of the appeal, and NBA was granted leave to intervene and be heard in the Supreme Court.
Jun-13	Supreme Court hearing
Dec-13	Supreme Court judgment dismissed the NZPork appeal

#### **About PRRS**

Porcine Reproductive and Respiratory Syndrome (PRRS) is a viral disease of pigs that emerged in the late 1980s and quickly spread through much of Europe, Asia and the Americas. PRRS has no impact on human health or any non-porcine species.

PRRS is not found in New Zealand, Australia, Sweden, Finland, and is also not reported in some developing countries without significant commercial pork industries. Most major producers and exporters of pork, including the USA, Canada and Denmark, have had PRRS for a number of years.

PRRS causes stillbirths and increases mortality of young pigs, and is regarded internationally as a significant disease in pig production. It primarily affects young pigs, decreasing weight gain and increasing mortality levels. This notwithstanding, major pork-producing nations such as the United States, Canada, Denmark and Spain have managed to maintain production levels despite the presence of PRRS primarily through the use of vaccines. Some countries, e.g. Sweden and Chile, have eradicated PRRS after its introduction.

PRRS is primarily spread by direct contact between pigs or in semen collected from infected pigs. New Zealand has long restricted the import of live pigs and pig semen. There are no import health standards for live pigs from

countries infected with PRRS, whereas import health standards for pig semen from countries with PRRS require testing of donor boars and semen.

# Import Health Standards development process

Under section 22 of the Biosecurity Act, the Director-General of MPI, following the recommendation of a Chief Technical Officer, can issue import health standards specifying the requirements to be met for the effective management of risk. The Act does not require that risk be eliminated. The Act does require consideration of New Zealand's obligations under the World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures (the WTO SPS Agreement).

MPI has comprehensive processes to ensure a consistent approach to identifying, assessing and managing risks is taken when developing Import Health Standards. This process conforms to the MPI policy on the application of precaution in managing biosecurity risks associated with importing risk goods.

As a Government department, MPI's role is to independently assess information on risk goods and mitigation measures, and determine an appropriate level of protection against risk.

Some Import Health Standards can have significant commercial, social and political impacts, leading to high levels of interest and input from stakeholders.

When passing the Biosecurity Act, Parliament made a conscious decision to place day-to-day decision-making on biosecurity risks with a department that had technical expertise in biological risks. This is reflected in the absence of a ministerial 'call-in' process.

While some New Zealand stakeholders suggest the Import Health Standard process is insufficiently rigorous, other stakeholders in New Zealand and elsewhere view the process as drawn-out and excessively risk-averse.

#### Changes to Pork Import Health Standards in 2001

In 2001, MPI became aware of new research showing that PRRS could be transmitted to healthy pigs by feeding them fresh meat from recently-slaughtered PRRS-infected pigs. In response, MPI issued new requirements in import health standards that pig meat from countries where PRRS is present must be cooked or cured prior to biosecurity release. The treatment could occur either offshore or at an MPI-approved facility in New Zealand.

Under the rules of international trade, this is termed a provisional measure. Such measures are allowable when there is insufficient evidence to support a full risk assessment. However, countries that impose provisional measure are required to seek new information and re-assess these measures when sufficient information is available.

# Import Risk Analysis for PRRS in Pork

In 2004, further research from Canada provided sufficient information for MPI to begin a full import risk analysis. This was provided to expert international reviewers in late 2005, and released for public consultation in July 2006.

The risk analysis concluded that the risk of PRRS can be effectively managed by cooking, curing, or restricting fresh pig meat imports to consumer-ready cuts that are unlikely to generate significant trimming waste. It indicated that with these management measures, the risk of the virus to the commercial pig population in New Zealand is negligible.

This conclusion was based on evidence that PRRS virus could be found in only a very small proportion (1.2%) of carcasses at slaughter, and that virus levels were reduced dramatically (>99%) by commercial slaughter, processing and handling. Virus levels continue to fall as meat is stored, and the virus is rapidly denatured by heating. Therefore only fresh, uncooked pork poses any risk.

Supporting this analysis of the scientific literature, MPI noted that tens of thousands of tonnes of pork were imported from countries where PRRS was present in the years prior to 2001. Much of this was in the form of

whole or part-carcasses, which were processed into retail cuts in New Zealand with no controls on the disposal of either meat or waste.

Despite these imports New Zealand has never recorded an outbreak of PRRS – a fact that is being used by other countries to support an argument that any sanitary measures on pork for PRRS are not justified.

Submissions from NZ Pork vigorously opposed the conclusion of MPI's risk analysis, taking the view that permitting any imports of untreated pig meat from countries with PRRS will inevitably lead to the establishment of PRRS in New Zealand.

Given NZPork's challenge of MPI's interpretation of the available science in a number of areas, MPI took the unusual step of referring this material to a number of international experts for comment. The feedback from these experts was considered by MPI and included as an appendix to the Review of Submissions published in June 2007.

MPI's Review of Submissions on the Import Risk Analysis did not recommend significant changes to the conclusions of the Import Risk Analysis.

Import risk analysis: Porcine reproductive and respiratory syndrome (PRRS) virus in pig meat (626 KB) Import Risk Analysis: Porcine reproductive and respiratory syndrome (PRRS) virus in pig meat - Review of Submissions (3346 KB)

In August 2007 a 'Further Science Report' was submitted to MPI by NZPork, detailing additional material that NZPork did not believe had been adequately considered by MPI. This included the results of quantitative modelling work that NZPork had commissioned Massey University epidemiologists to produce. MPI concluded that this information did not raise any matters that significantly affected the conclusion of the Risk Analysis.

#### **Draft Import health Standards**

Following completion of the Import Risk Analysis, MPI prepared draft Import Health Standards for consultation. These Standards translate the recommendations of the Import Risk Analysis into a working document suitable for use by offshore producers, importers and MPI border staff.

Four draft Import Health Standards were released in November 2007, covering pork, products made from pork, and pig meat by-products from the European Union, Canada, the USA and Sonora State of Mexico.

These were accompanied by additional background information, highlighting further analysis that had been undertaken.

Additional background information (82 KB)

Following consultation, MPI released a review of submissions on draft Import Health Standards in March 2009.

Review of submissions on Draft Import Health Standards for pig meat and pig meat products (2934 KB) MPI's response to the Further Science Report was published as an appendix to the Review of Submissions on draft Import Health Standards in March 2009 (see the above link).

Following this, in April 2009 MPI issued provisional Import Health Standards for pig meat from the European Union, Canada, USA and Sonora State of Mexico and in May 2009 NZPork requested a review of the provisional Standards, under section 22A of the Biosecurity Act 2003.

As with consultation on the Import Risk Analysis, submissions were highly polarised. Some broadly supported the measures, although some argued that no sanitary measures to exclude PRRS were necessary. Others strongly opposed any provisions allowing the import of uncooked pork.

Following the Review of Submissions, MPI finalised the Standards, Known as 'Provisional Import Health Standards', these are released to stakeholders for 10 working days prior to taking effect. International trade partners are notified of these provisional standards.

An amendment to the Biosecurity Act in 2008 allows for further review by an Independent Review Panel to be requested by a New Zealand stakeholder at this point (see below).

# **Independent Review Panel**

In 2008, the Biosecurity Act was amended to allow a further review stage prior to an Import Health Standard taking effect. The introduction of Section 22A of the Act made it possible for a party that had previously been consulted during the development of a standard to request an Independent Review Panel be appointed to consider whether there has been 'sufficient regard to the scientific evidence'.

The Director-General is responsible for deciding whether a panel is appointed. Where one is appointed that Panel reports back to the Director-General, who is required to take into account the Panel's recommendations, but is not obliged to accept them.

In October 2009 MPI's Director-General appointed the pork Independent Review Panel, made up of three international experts and a New Zealand Chair.

Terms of Reference for Independent Review Panel (96 KB)

On 31 March 2010 the Independent Review Panel reported back to the Director-General, Its report made 29 recommendations covering a wide range of topics, with a strong focus on quantitative modelling and working in a more collaborative manner with industry.

Report of the Independent Review Panel on the provisional Import Health Standards for pig meat and pig meat products for New Zealand (618 KB)

The Panel considered that MPI had adequately considered most but not all of the scientific evidence. Recommendations were made on addressing gaps in data, and carrying out additional modelling work. The Panel also made recommendations on changes to the process by which Import Health Standards are developed, including a more collaborative relationship with industry.

# MPI Response to the Independent Review Panel

In August 2010 MPI's Director-General announced a response to the Panel's report. Key points were:

- Structural and process recommendations were directed to working groups already reviewing those
- Other recommendations assessed on grounds of materiality to the decision on pork imports.
- Some limited gathering of additional information where this could be done quickly and cost-effectively.
- MPI to carry out quantitative modelling and sensitivity analysis using model submitted by NZPork in their 'New Science' package.
- An Expert Working Group to be appointed to review MPI's modelling, with nominations sought from stakeholder groups.

Chief Technical Officer's Advice to Director-General on Report of Independent Review Panel (6466 KB)

The further quantitative risk modelling work was carried out by MPI staff, using an overall model structure based on the NZPork 2007 model and assumptions that MPI considered were closely based on the available evidence. Whereas NZPork's model found that there would be multiple incursions per year. MPI found the mean time between incursions was measured in decades (at worst) or in millennia (at best).

In September 2010 MPI provided domestic and international stakeholders with draft terms of reference for an Expert Working Group, and invited nominations for experts to participate in a process of meeting by teleconference to review the further quantitative risk model. The experts did not reach a consensus on the likelihood of PRRS introduction, although common ground was established on some technical matters. Each member submitted their own review of the quantitative risk model, and an overall summary was developed by MPI.

Report of the Expert Working Group (5412 KB)

MPI contracted an expert risk analysis consultancy firm to develop a final model taking full account of the Expert Working Group report.

The Director-General of MPI carefully considered the work undertaken in response to the Independent Review Panel's report and the resulting conclusions. His decision determining the matters in dispute was made on 11 April 2011 in a 32 page document supported by over 900 pages of annexed analyses, reports and briefings.

MPI Director General decision in accordance with Section 22A(3) of the Biosecurity Act 1993 regarding the pork import health standards (9359 KB)

# Import Health Standards for pig meat and pig meat products issued

Following the recommendation of the MPI Chief Technical Officer, on 13 April 2011 the Director-General issued four Import Heath Standards for pig meat, pig meat products and by-products from Canada, the EU, Mexico and the USA.

- Recommendation for the issue of import health standards (2245 KB)
- Importing Pig By-Products from Canada and/or the United States of America
- Importing Pig Meat and Pig Meat Products for Human Consumption from Canada and/or the United States of America
- Importing Pig Meat and Pig Meat Products for Human Consumption from the European Union
- Importing Pig Meat and Pig Meat Products for Human Consumption from the Sonora State Of Mexico

MPI considers the risk of introducing PPRS will be effectively managed through the application of the measures in the Import Health Standards. This consideration is based on the 2006 risk analysis and is supported by the quantitative modelling work subsequently undertaken on the recommendation of the Independent Review Panel.

The measures for uncooked pork remain as issued in the provisional standards i.e. restrict imports of raw pig meat to consumer-ready cuts weighing no more than 3kg, with lymph nodes removed, derived from healthy pigs that have been subject to ante and post-mortem inspection and certified for human consumption by official veterinarians in overseas countries.

A minor amendment has been made to the specification of the requirements in relation to pH-cured pork in the final import health standards to take appropriate account of the published science on viral stability. The change aligns with manufacturing norms.

# Legal Challenge

NZPork applied to the High Court for judicial review of statutory decisions related to the issue of the new import health standards. A review was granted in May 2011. The Court also granted interim relief, preventing any import of pork under the new Standards until the case could be heard.

The substantive hearing was held in August 2011 at the High Court in Wellington and on 3 May 2012 the Court ruled in favour of MPI and awarded costs.

The NZPork and MPI submissions to the High Court are available below, along with the judgment of the High Court.

- NZ Pork submissions as applicant (2843 KB)
- MAF's submissions as respondent (5907 KB)
- MAF's supplementary submissions as respondent (1145 KB)
- High Court judgment

In May 2012, NZPork appealed the High Court decision to the Court of Appeal At NZ Pork's request the High Court granted further interim orders in June 2012, which stayed the introduction of the parts of the new import health standards that relate to imports of "consumer ready cuts" of raw pork from countries where PRRS is present until the Court of Appeal hearing.

The Court of Appeal hearing was heard on 28 November 2012.

The NZPork and MPI submissions are available below.

- MPI's submissions in opposition to interim relief (1197 KB)

On 18 March 2013, the Court of Appeal dismissed NZ Pork's appeal; the judgment of the Court of Appeal is available below:

The Court of Appeal judgment (298 KB)

On 12 April 2013 NZPork applied to the Supreme Court for leave to appeal the Court of Appeal decision. MPI opposed NZPork's application.

On 15 May the NZPork was granted leave to appeal to the Supreme Court, on 31 May 2013 the Supreme Court granted the NZ Pork Board further interim relief pending determination of the appeal. In addition the National Beekeepers Association (NBA) applied to the Court to intervene in this case, and the Court allowed that on the basis that the matters on which the NBA wished to make submission may be helpful to the Court.

The Supreme Court hearing took place on 26 June 2013.

Submissions to the Supreme Court by NZPork, NBA and MPI are available below:

- Submissions of NZPork as appellant (418 KB)
- Submissions of National Beekeepers Association (329 KB)
- Submissions of MPI as respondent (3192 KB)

The Supreme Court delivered its judgment on 20 December 2013. In summary, the Supreme Court dismissed the appeal from NZPork, by a majority decision.

The press release from the court and the judgment are available below:

- Supreme Court press release (79 KB)
  Supreme Court Judgment (454 KB)

As interim relief was granted only until the decision was made, this judgment means that interim relief has now lapsed.

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