IN THE SUPREME COURT OF NEW ZEALAND

SC 36/2013
[2013] NZSC 154

BETWEEN	THE NEW ZEALAND PORK INDUSTRY BOARD Appellant
AND	THE DIRECTOR-GENERAL OF THE MINISTRY FOR PRIMARY INDUSTRIES First Respondent
AND	THE CHIEF TECHNICAL OFFICER AND BIOSECURITY NEW ZEALAND Second Respondents
AND	NATIONAL BEEKEEPERS ASSOCIATION OF NEW ZEALAND INC Intervener

Hearing:	26 June 2013
Court:	Elias CJ, McGrath, William Young, Glazebrook and Arnold JJ
Counsel:	F M R Cooke QC and J B Kaye for Appellant C R Gwyn and K M Muller for First and Second Respondents M S R Palmer and M Smith for Intervener
Judgment:	20 December 2013

JUDGMENT OF THE COURT

A **The appeal is dismissed.**

B **The appellant is to pay costs of $25,000 to the first and second respondents collectively, plus reasonable disbursements as fixed by the Registrar.**

REASONS

Para No

ELIAS CJ

[1] The Director-General of the Ministry for Primary Industries[1] is empowered by s 22(1) of the Biosecurity Act 1993 to set import health standards for the effective management of risks associated with the importation of risk goods.[2] "Risk goods" are defined to include "any organism … that may … cause unwanted harm to natural and physical resources or human health in New Zealand".[3] Before an import health standard can be made, the Director-General is obliged to obtain a recommendation from a chief technical officer[4] after the chief technical officer has consulted with those the chief technical officer considers to be "representative of the classes of persons having an interest in the standard".[5] Under s 22A of the Act, enacted in 2008,[6] if a person consulted by the chief technical officer raises "a significant concern" about the science that has been employed, the Director-General may obtain a report from an independent review panel "to review whether, in developing an import health standard, there has been sufficient regard to the scientific evidence" about which the "significant concern" has been raised.[7] On receiving the report, the Director-General is required, "as soon as is reasonably practicable" to "determine the issue in dispute after taking into account the findings and recommendations of the independent review panel, giving reasons for that determination".[8]

[2] In 2001, after an outbreak of foot-and-mouth disease in England and of Porcine Reproductive and Respiratory Syndrome (PRRS) in South Africa, a new

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1 The Ministry of Agriculture and Forestry merged with the Ministry of Fisheries and the New Zealand Food Safety Authority and was renamed the Ministry for Primary Industries as of 30 April 2012.

2 Biosecurity Act 1993, s 22(1). In these reasons, references to the Biosecurity Act are to the Act prior to the 2012 amendments, unless otherwise indicated. See below at [11]–[14].

3 Section 2.

4 Section 22(1).

5 Section 22(6).

6 Biosecurity Amendment Act (No 2) 2008, s 6.

7 Section 22A(1).

8 Section 22A(3).

scientific study suggested that the destructive viruses, including PRRS, can be transmitted through the ingestion by pigs of infected raw meat (and not simply by contact between live pigs or through infected semen, as had previously been thought). The Director-General for the Ministry then put in place a provisional import health standard which prevented the importation of raw pig meat from countries where the virus PRRS has been detected in pigs. Because of the need for urgency in responding to the new scientific information, the standard was adopted as a precautionary and interim response on an incomplete assessment of risk. It was based on a draft import risk analysis by the Ministry as to the risk of the virus entering New Zealand which did not extend to the likely effects if pigs in New Zealand were exposed to the virus, as is required by s 22(5)(b).

[3] PRRS is highly contagious and destructive. New Zealand and Australia are two of only five countries in the developed world which are known to be free of it. It has the capacity to cause substantial harm to the pork industry.

[4] The appeal concerns the import health standards issued by the Director-General on 13 April 2011. They are substantially the same as the provisional import health standards issued in 2009, which were the ultimate replacements for the 2001 provisional import health standards. The new standards were adopted after a process of risk assessment and consultation which is outlined in what follows.

[5] The standards set in April 2011 permit uncooked pig meat to be imported from the European Union, Canada, the United States and the Sonora State of Mexico (in all of which the virus is endemic) provided specified conditions are met. The two principal conditions are that the meat either consists of consumer-ready cuts packaged for direct retail sale not exceeding 3 kg per package (and excludes minced meat, the head and neck, and lymph tissues) or is processed in an approved transitional facility in New Zealand to meet the standards set for direct importation.[9] The purpose of confining the raw pig meat imported to high value retail cuts and of providing that larger raw pig products be first processed into such cuts in an approved facility in New Zealand is to reduce the risk that infected raw meat will be

[9] Transitional facilities must be approved under s 39 of the Biosecurity Act.

fed to pigs in New Zealand. Key to the decision of the Director-General in setting the 2011 standards is his assessment that the risk to New Zealand is effectively managed by the conditions set in the standards.

[6] The issue on the appeal is not whether the standards set in April 2011 are appropriate to manage the risk effectively. The only issue for the Court is whether the statutory processes, designed to assess and manage biosecurity risk effectively, have been properly followed.

[7] Insistence on strict adherence to the procedures required by the statute is not to elevate form over substance.[10] The requirement that specified processes be followed reflects the legislative judgment that those processes enable better substantive decision-making in an area where assessment of risk is necessarily a matter of judgment incapable of exact proof and where the adverse consequences of faulty judgment may be very damaging to New Zealand because of its dependency on primary production and the advantages it enjoys because of its remoteness. The system employed depends on private contribution to the decision-making by interested parties, in a form of regulation not uncommon in recent years, which harnesses additional expertise outside government and transfers some costs of government regulation.

[8] Well-known and costly errors in management of biosecurity in recent years have occurred despite the statutory controls available to the Director-General. As a direct result, amendments to the legislation in 2008 provided for more extensive participation in risk management assessment under s 22A, to ensure that contentious biosecurity decisions are made on the best available scientific information and that the science is subject to some independent scrutiny. A purpose of the independent review process introduced in 2008 with the new s 22A was described by the Chair of the Select Committee which recommended its adoption as being to address the problem that the Ministry was perceived as being "judge and jury on the issue".[11]

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[10] As was suggested in the decision appealed from by Harrison and Stevens JJ: *New Zealand Pork Industry Board v Director-General of the Ministry of Agriculture and Forestry* [2013] NZCA 65 (Harrison, Stevens and White JJ) [*New Zealand Pork Industry Board* (CA)] at [96]–[97].

[11] (20 March 2008) 646 NZPD 15145.

[9] It is clear from ss 22 and 22A of the Act that industry participants have an important contribution to make in setting import health standards. While no doubt they can be expected to represent their own interests, the debates at the time of the 2008 amendments do not suggest the views of industry participants are to be discounted for that reason and clearly there is common cause with the Ministry in seeking to manage risk of harm.[12] Conversely, the debates in Parliament treat the Ministry itself as a participant with its own views and constraints which have sometimes impeded its assessment of risk and whose assessments therefore benefit from independent and public scrutiny by others with the capacity and resources to make such contribution.[13] With this background, I do not think that it is helpful or appropriate to depreciate the interest of producers in the assessment of risk and its effective management because of their self-interest. The legislation, and the circumstances which led to its adoption, indicate the importance placed on the process prescribed and the participation of those affected.

[10] The appeal turns on the application of ss 22 and 22A of the Biosecurity Act. For the reasons to be given, and in disagreement with the other members of the Court, I am of the view that s 22 was not followed and that the import health standards issued on 13 April 2011 are invalid.

The Biosecurity Act 1993

[11] The import health standards in issue were adopted under s 22 of the Biosecurity Act and after the process provided for in s 22A. Those provisions have since been repealed by the Biosecurity Law Reform Act 2012 which replaced them with equivalent provisions now contained in ss 22 to 24K of the Biosecurity Act. It has been accepted that the present appeal turns on the provisions in force at the time the import health standards challenged in the proceedings were adopted by the Director-General.

[12] The changes in the legislation do not affect the substance of the issues on the appeal, but they are organised in accordance with the sequence to be followed in developing an import health standard or in deciding not to issue one. The sequence

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12 See (1 April 2008) 646 NZPD 15201–15202.
13 See (1 April 2008) 646 NZPD 15204.

may have been less easy to see in the provisions as enacted before 2012, although they were to the same effect. The former s 22 ("Import health standards") has now been reorganised and split into s 22 ("Meaning of import health standard"), s 23 ("From draft to recommendation"), and s 24A ("Issue"). The former s 22A ("Process for independent review panel to be established") is in substance reproduced, although reorganised, in the present s 24 ("Review") and is now located before s 24A ("Issue"), making clear the sequence of decision-making (a little obscure in the former provisions which began with the issue of an import health standard and only then described the processes to be followed).

[13] In the new s 24A, it is made explicit (what may not have been as easy to follow in the layout of the former provisions) that the Director-General's decision to issue an import health standard following the recommendation of the chief technical officer is a decision taken "[*a*]*fter* … complying with section 24(4) [the determination of the dispute referred to a review panel under the former s 22A], if it applies" (emphasis added). The two determinations, where the review panel process is invoked, are sequential and distinct.

[14] In what follows the questions raised in the appeal are dealt with by reference to the pre-2012 provisions, the course followed by the Court of Appeal and by counsel in their submissions. I have referred to the 2012 provisions only to point out that they are consistent with the meaning I attribute to the provisions in issue here.

[15] The importation of "risk goods" is dealt with under Part 3 of the Act. Its purpose is described as being "to provide for the effective management of risks associated with the importation of risk goods".[14] Section 22(1) permits the Director-General to set import health standards "specifying the requirements to be met for the effective management of risks associated with the importation of risk goods before those goods may be imported". The Director-General is not obliged to set an import health standard (without which such goods cannot be imported) if he considers that the purpose of the Act would not be met by any requirements that could be imposed.[15] The Director-General may set import health standards only

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14 Section 16.
15 Section 22(3).

"following the recommendation of a chief technical officer".[16] To the extent relevant to the appeal, s 22 provides:

> **22 Import health standards**
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> (1) The Director-General may, following the recommendation of a chief technical officer, issue an import health standard specifying the requirements to be met for the effective management of risks associated with the importation of risk goods before those goods may be imported, moved from a biosecurity control area or a transitional facility, or given a biosecurity clearance; and may, in a like manner, amend or revoke any import health standard so issued.
>
> (1A) An import health standard issued under this section applies to goods the importation of which involves, or might involve, an incidentally imported new organism.
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> …
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> (3) Nothing in this Act obliges the Director-General to have an import health standard in force for goods of any kind or description if, in the Director-General's opinion, the requirements that could be imposed on the importation of those goods would not be sufficient to enable the purpose of this Part to be met if the importation of those goods were permitted.
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> (4) An import health standard issued under this section may apply to goods of a certain kind or description imported from—
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> (a) a country or countries specified in the import health standard; or
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> (b) countries of a kind or description specified in the import health standard; or
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> (c) all countries; or
>
> (d) a location or locations specified in the import health standard.
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> (5) When making a recommendation to the Director-General in accordance with this section, the chief technical officer must have regard to the following matters:
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> (a) the likelihood that goods of the kind or description to be specified in the import health standard may bring organisms into New Zealand:
>
> (b) the nature and possible effect on people, the New Zealand environment, and the New Zealand economy of any organisms that goods of the kind or description specified in the import health standard may bring into New Zealand:

[16] Section 22(1).

(c) New Zealand's international obligations:

(d) such other matters as the chief technical officer considers relevant to the purpose of this Part.

(6) Before making a recommendation to the Director-General on the issue or amendment of an import health standard, the chief technical officer must, unless the standard needs to be issued or amended urgently, or unless the chief technical considers that the amendment is minor, consult with those persons considered by the chief technical officer to be representative of the classes of persons having an interest in the standard.

(7) The consultation may be on the import health standard or on a document that analyses or assesses the risks associated with the goods or class of goods to which the goods belong.

…

[16] In making a recommendation to the Director-General, the chief technical officer must have regard to "the likelihood that [the goods] may bring organisms into New Zealand"[17] and the likely effect of such organisms on "people, the New Zealand environment, and the New Zealand economy".[18] The chief technical officer must also have regard to "New Zealand's international obligations"[19] and to "such other matters as the chief technical officer considers relevant to the purpose of this Part".[20]

[17] Unless there is some urgency or the recommendation concerns amendment to a standard which is "minor", the chief technical officer must, under s 22(6), first "consult with those persons considered by the chief technical officer to be representative of the classes of persons having an interest in the standard". This consultation "may be on the import health standard or on a document that analyses or assesses the risks associated with the goods or class of goods to which the goods belong".[21]

[18] Section 22A of the Act provides a process for reviewing whether, "in developing an import health standard, there has been sufficient regard to the scientific evidence about which a person consulted under section 22(6) has raised a significant concern":

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17 Section 22(5)(a).
18 Section 22(5)(b).
19 Section 22(5)(c).
20 Section 22(5)(d).
21 Section 22(7).

22A Process for independent review panel to be established

(1) The Director-General must, by notice in the *Gazette*, set out the process by which an independent review panel is to be established to review whether, in developing an import health standard, there has been sufficient regard to the scientific evidence about which a person consulted under section 22(6) has raised a significant concern.

(2) The notice required by subsection (1) must cover the following matters:

(a) the criteria for setting up an independent review panel; and

(b) how the Director-General will appoint an independent review panel, including the knowledge and experience required for appointees; and

(c) the procedures to be followed by—

(i) a person eligible to seek a review under subsection (1); and

(ii) an independent review panel, in undertaking its review; and

(d) the reporting requirements for an independent review panel.

(3) The Director-General must receive any report from an independent review panel and, as soon as is reasonably practicable, determine the issue in dispute after taking into account the findings and recommendations of the independent review panel, giving reasons for that determination.

…

[19] As is provided in s 22A(3), on receipt of a report obtained under this process of independent review, it is the responsibility of the Director-General to "determine the issue in dispute". He must give reasons for the determination.

[20] The process the Director-General was obliged by s 22A to adopt and publish was published in the *Gazette* on 26 June 2008.[22] Clause 9 of the *Gazette* notice deals with the decision to grant a request for a review. In considering whether to accept a request for review, the Director-General "must take into account":

(a) the extent to which the scientific evidence is or may be material to the measures in the proposed import health standard;

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[22] "Biosecurity (Process for Establishing Independent Review Panel) Notice 2008" (26 June 2008) 104 *New Zealand Gazette* 2765.

(b) the extent to which the request for review appears to be based on credible scientific evidence;

(c) whether the evidence has been the subject of an earlier review; and

(d) any other relevant matter.

Background

[21] As has been mentioned, the provisional standards were adopted in 2001 as a precautionary measure based simply on new appreciation of the risk of incursion of the PRRS virus through raw imported pig meat fed to pigs in New Zealand. Further work was necessary before a non-urgent standard could be adopted under s 22. Further work was also necessary to justify the restriction adopted for the interim, or any modification of it, in order to comply with New Zealand's international obligations, particularly under the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) adopted by the World Trade Organisation.[23] Before 2012 the chief technical officer had a general duty under s 22(5)(c) to "have regard to New Zealand's international obligations". That is a duty now made explicit in relation to the SPS Agreement under the new s 23(4)(c), enacted in 2012, which requires the chief technical officer to be "satisfied that the requirements proposed for inclusion in the standard are consistent with New Zealand's obligations under the SPS Agreement".

[22] Under the SPS Agreement, restriction of trade for biosecurity reasons is permitted only where standards are justified by scientific principles and evidence,[24] including as to risk assessment,[25] and then only to the extent necessary to protect human, animal or plant life or health.[26] Such standards must not amount to a disguised restriction on trade.[27] Article 5 of the SPS Agreement permits provisional measures to be put in place "[i]n cases where the relevant scientific evidence is insufficient" on the basis of the available information.[28] The precautionary provisional standard set in 2001 was justified on this basis. Where a provisional

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23 The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (signed 15 April 1994, entered into force 1 January 1995).
24 Article 2.2.
25 Article 5.1.
26 Article 2.2.
27 Article 5.6.
28 Article 5.7.

standard is put in place, however, states are obliged to "seek to obtain the additional information necessary for a more objective assessment of risk" and to "review the sanitary or phytosanitary measure accordingly within a reasonable time".[29] It was therefore incumbent on the Ministry once it had put in place the provisional standard to obtain the information it needed to make "a more objective assessment of risk" and to review the provisional standard.

[23] The scientific assessment of risk and consideration of its effective management in review of the provisional 2001 measure took some time. Eventually, in July 2006, the Ministry released for consultation a paper assessing the risk of importing pig meat from countries with the virus, "Import Risk Analysis: Porcine reproductive and respiratory syndrome (PRRS) virus in pig meat".[30] The analysis concluded that the likelihood of the virus being introduced through chilled or frozen imported pig meat was "low"[31] but not negligible.[32] It was acknowledged that, if the virus were introduced to New Zealand, the consequences would be "significant on affected farms, particularly in breeding units".[33] The risk analysis therefore accepted that some sanitary standards were required. It pointed to the fact that the feeding of raw meat to pigs was illegal under the garbage feeding regulations[34] (so that "an exposure pathway" would exist only on those farms not complying with the regulations) [35] and that, if infection did occur, "the likelihood of spread to other pig farms would be low as long as standard biosecurity practices were observed".[36]

[24] On the basis of this analysis of risk, the Ministry proposed that the ban on importing raw pig meat from countries affected by the PRRS virus be relaxed to permit the import of "consumer-ready, high value cuts" from countries not free of PRRS.[37] In addition to these "consumer-ready, high value cuts", imports of other raw pig meat from the same countries was to be permitted for the purpose of further

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29 Article 5.7.
30 Noel Murray and Howard Pharo *Import Risk Analysis: Porcine reproductive and respiratory syndrome (PRRS) virus in pig meat* (Ministry of Agriculture and Forestry and Biosecurity New Zealand, 25 July 2006) [2006 *Import Risk Analysis*].
31 At [1].
32 At [4].
33 At [4].
34 Biosecurity (Meat and Food Waste for Pigs) Regulations 2005.
35 At [2].
36 At [3].
37 At [4].

processing on arrival, "in an officially approved facility, into consumer-ready high value cuts".[38] The reason for the restriction to consumer-ready high value cuts was the view that such cuts minimised trimming or cutting during preparation and were therefore less likely to generate raw waste which might be fed to pigs.[39]

[25] The New Zealand Pork Industry Board is a statutory body set up under s 4 of the Pork Industry Board Act 1997 with the object under s 5 "to help in the attainment, in the interests of pig farmers, of the best possible net ongoing returns for New Zealand pigs, pork products, and co-products", while being obliged to "have regard to the desirability of the pork industry's making the best possible net ongoing contribution to the New Zealand economy". The Board's functions include increasing demand for New Zealand pork products in existing and new markets,[40] helping to "maintain the confidence of consumers of pork products in the New Zealand pork and pig industries"[41] and improving access to overseas markets.[42] Four directors are elected by pig farmers and up to two are appointed by the Minister because of relevant expertise.[43] The adoption of a replacement import health standard to manage the risk to the New Zealand pig population of the introduction of PRRS was a matter on which the Board's functions made it "representative of the classes of persons having an interest in the standard" under s 22(6), requiring the chief technical officer to consult with the Board before making his recommendation to the Director-General.

[26] The Board was concerned about the assessment of risk which underlay the proposals for a new import health standard published by the Ministry. It expressed the view that kitchen and commercial waste is commonly fed to pigs in New Zealand. It pointed to a review by the Ministry which said that regulations to control the feeding of scraps to pigs[44] were unlikely to be effective, whether or not there was awareness of the regulations (a circumstance contributed to by the nature

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38 At [4].
39 At [5.2.2.2].
40 Section 6(1)(a).
41 Section 6(1)(b).
42 Section 6(1)(c).
43 Section 13(2).
44 Clause 5 of the Biosecurity (Meat and Food Waste for Pigs) Regulations provides that pigs must not be fed untreated (raw) meat or food waste that contains or (under (b) of the definition of "untreated food waste" in s 4) has come into contact with untreated meat.

of pig farming in New Zealand in small populations).[45] The Board considered that there was insufficient scientific justification for the proposed standard and that it was speculative for the Ministry to say that the risk of incursion of the virus through the feeding of imported scraps to pigs would be acceptably reduced by confining imports to high value cuts or limiting processing in the way proposed.

[27] As a result of the feedback it received on its July 2006 paper, the Ministry commissioned a peer review of the risk assessment from international experts, which took until June 2007. It released its review of the submissions it had received on the risk assessment in June 2007. In August 2007 the Board commissioned Dr Neumann and Professor Morris, both veterinary scientists with experience in quantitative modelling of disease in animals, to model a quantitative assessment of the risk of the introduction of the PRRS virus through the importation of raw pig meat from countries affected by the virus. Their model predicted an average of 4.3 outbreaks of PRRS a year from the feeding of infected raw imported pig meat to pigs in New Zealand. The report obtained was given to the Director-General but did not lead to a change in the proposal. On 12 November 2007, the Ministry released draft import health standards for pig meat. Under them, import of "ready-to-cook, high value cuts of pig meat" would be permitted from the European Union, Canada, the United States, and the Sonora State of Mexico. The Board responded with a submission seeking rejection of the draft standard, relying on the quantitative risk model developed by Dr Neumann and Professor Morris. Following further consultation, the Director-General on 7 April 2009 published further provisional import health standards adopting the standard as proposed in the drafts upon which it had consulted.

[28] By that time, the Biosecurity Amendment Act (No 2) 2008 had inserted s 22A into the Biosecurity Act and the Director-General had published the independent review panel notice in the *Gazette*.[46] On 28 May 2009 the Board requested the Director-General establish an independent review panel under s 22A, identifying nine matters of concern to it relating to the adequacy of the scientific evidence. On 7 August 2009 the Director-General agreed to the Board's request and set up a

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45 2006 *Import Risk Analysis*, above n 30, at [4.2.5]–[4.2.5.3].

46 *Gazette* notice, above n 22.

review panel. The review panel was chaired by a New Zealand Queen's Counsel and comprised in addition Professor Katharina Stärk (from the Royal Veterinary College, United Kingdom), Professor John Wilesmith (a retired professor and specialist in veterinary epidemiology from the United Kingdom) and Professor James McKean (a veterinary epidemiologist of Iowa State University, United States).

[29] In September, terms of reference for the review panel were provided. Under them, the review panel was asked to review whether sufficient regard had been paid by the Ministry to the scientific evidence in nine areas (the first eight of which had been suggested by the Board in its request):

> (a) The identification and analysis of potential hazards associated with the importation of pig meat and pig meat products.
>
> (b) The likelihood that meat from slaughter weight pigs will contain infectious PRRS virus.
>
> (c) The impact of changes to volumes of trade in pig meat as a result of the proposed changes in the [import health standards].
>
> (d) The impact of changes to the volume and distribution of the waste stream as a result of the proposed changes in the [import health standards].
>
> (e) The likelihood that PRRS-infected imported pig meat will be fed to [New Zealand] pigs and cause infection.
>
> (f) The structure and inter-relatedness of the New Zealand commercial and non-commercial pig industries, and consequent exposure and spread risks.
>
> (g) Importance and likelihood of aerosol and 'area' spread of PRRS virus between herds.
>
> (h) Quantitative modelling of the risk of PRRS virus exposure and consequence, using the model developed during the [import risk analysis/import health standards] process.
>
> (i) Each of the above issues sits within the context of the overall assessment of risk. The Panel should consider whether [the Ministry's] overall treatment of the issues was reasonably open on all the evidence.

[30] The review panel met by teleconference and videoconference and exchanged emails between November 2009 and March 2010. Its report to the Director-General was presented on 31 March 2010.[47]

The review panel findings and recommendations

[31] In its report, the review panel indicated that it had confined itself to the threat of the PRRS virus alone, since a study of other "potential hazards" (which had been included in the terms of reference) was "not feasible within the available time" and the review panel had been provided with information only about PRRS. With respect to other hazards, it suggested greater transparency around hazard identification and better communication about risks in general.

[32] The review panel recommended that the import risk assessment should be redone to ensure that it took into account the relevant and current science and either filled or acknowledged and modelled for gaps in the analysis. It took the view that the Ministry had insufficiently acknowledged the limitations in scientific knowledge particularly in relation to infectiousness and treatment of affected pig meat. It considered that there were gaps in important parts of the risk analysis, including in assessment of the volume of trade likely. The Ministry's risk assessment "did not address the impact of trade volume directly", despite its importance because of the sensitivity of the risk estimate towards trade volume and the likelihood that risk of introduction would increase with a rise in the volume of trade. Nor did the Ministry sufficiently explain why it had assessed the extent of discarded pig meat at 3.8 per cent when a study in the United Kingdom had considered that its assessment of 7 per cent (based on survey) was an underestimate. This factor was "of key significance in [the Ministry's] risk assessment". The Ministry had justified the difference on the basis of an "unsubstantiated assumption" that a proportion of the United Kingdom cuts would be of cuts greater than 3 kg (which the review panel thought hard to reconcile with the dominance of supermarket sales in the United Kingdom, in which smaller cuts predominate).

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[47] *Report of the Independent Review Panel on the Provisional Import Health Standards for Pig Meat and Pig Meat Products for New Zealand* (31 March 2010).

[33] The review panel expressed concern that "there is no reliable estimate presented of the amount of uncooked pork/pigmeat which is likely to be discarded from the various sources in New Zealand". It thought it surprising that effort had not been made "to fill gaps in the necessary information base", because the gaps created uncertainty in the risk analysis "especially where there is no assessment of the sensitivity of the analysis to the assumptions made on estimates".

[34] Nor was there adequate information about the New Zealand pig population, such as was needed to assess the risk of spread of any infection and to justify the Ministry's view that observance of biosecurity measures would adequately manage the risk of spread. The review panel identified the need to obtain the current population data for pigs and obtain better data on farm size, type and location "in order to reduce the uncertainty about the epidemiological and economical consequences of a potential PRRSv introduction". It identified recent clinical experiences in the United States and elsewhere that suggested the Ministry was "overly optimistic" in its view that movement limitations and biosecurity measures would contain virus movement.

[35] The review panel considered that the Ministry's "qualitative" assessment should have been supplemented by a "quantitative" analysis of risk, as the Ministry's external reviewer had also recommended (although it thought that some of the uncertainties used in the sensitivity analysis in the Neumann model gave some validity to the Ministry's criticisms of it). It recommended that the Neumann quantitative model be "updated with the currently available information by a joint technical working group, including epidemiologists experienced in quantitative risk assessment named and agreed by MAF and stakeholders, including [the Board]" and that the Ministry consider the use of empirical information of the extent to which infected pig meat might be fed to pigs to update the risk assessment. Recent studies since the risk assessment was undertaken by the Ministry needed to be factored in (especially relating to the percentage of pig meat discarded as waste and the spread of infection by area and air) in order to ensure that the risk assessment "is based on more robust scientific and epidemiological data". Of some importance is the review panel's recommendation that the results of the further modelling "should be presented in a report and should then be integrated in a revised version of the [import

risk assessment]". (It acknowledged that the conclusions of the original import risk assessment might remain unchanged.) Significantly, it said that "[i]f significant uncertain and influential model inputs are identified, the collection of additional data should be considered".

[36] The review panel was critical of the lack of transparency in the selection of independent reviewers by the Ministry and the "overall process involved in obtaining and reviewing the relevant scientific evidence". It considered that "in some areas [the Ministry] made assumptions based on relatively little data". To the extent that this was unavoidable, the lack of knowledge needed to be stated clearly, and needed to be taken into account in "a level of sensitivity for the key elements". It acknowledged the limited resources available to the Ministry but expressed some concern that the Ministry had been "too hasty" in dismissing comments adverse to its position, including comments it had solicited from reviewers. It had "made assumptions for which there was considerable uncertainty and for which no or limited effort was reported to substantiate or refute in the course of conducting the [import risk assessment]". The review panel took the view that the reassessments it recommended "would not take more than 6 to 9 months to complete, depending on the resources available". And it recommended cooperation in meeting the recommendations between the Ministry and the Board.

Responding to the review panel recommendations

[37] In April 2010 the Ministry convened a meeting of stakeholders, including representatives of the Board, to discuss the findings of the review panel, the key recommendations of the report, and how the Ministry might respond to its recommendations. At the meeting the Board took the view that, while it was supportive of a stakeholder working group to progress the recommendations through providing advice to the Director-General, there should be a new risk analysis rather than an attempt to "backfill" the existing import health standard. There was discussion about the key issues raised by the Ministry in the agenda for the meeting and an indication by representatives of the Ministry that it was undertaking further work.

[38] In an update of 2 July, the Ministry advised the Board that it declined its offer to have further input into the preparation of the advice for the Director-General. It advised that the Ministry was considering what the review panel had recommended as to quantitative risk modelling and expected to be in a position to provide its advice to the Director General "in the near future". It advised that the Director-General "has determined that no further stakeholder input will be required prior to the Director-General deciding how he wishes to respond to the review panel's recommendations", and that "[s]hould the Director-General decide that further work is required, it is likely that there will be an opportunity at that stage for further input from stakeholders".

[39] Part of the work undertaken in the meantime by the Ministry was refinement of the quantitative model originally put forward by Dr Neumann and Professor Morris, as the Ministry's communications had indicated would be happening. The Ministry sought input from some of the expert review panel members on its adjustment for some inadequacies in the values entered into the original model – such as the failure to acknowledge in the assessment of pig meat imports that a proportion of imported pig meat would continue to come from other countries that are free of PRRS, namely Australia, Finland and Sweden. The Ministry indicated that its work showed that the four most influential input variables in the sensitivity analysis were number of meals consumed annually by each pork-consuming household, proportion of pig carcasses likely to be contaminated at the time of slaughter, the concentration of PRRS virus in contaminated carcasses at slaughter, and the proportion of pork in a meal that is discarded as fresh raw scrap. The first variable was the same as that used by Neumann. The second and third variables were said to reflect the current state of knowledge and it was thought that further studies were unlikely to provide a change in understanding. The fourth variable (the proportion of raw pork trimmed off and discarded as raw meat prior to cooking) was different in that there was no data to substantiate the 10 per cent assumption identified by Neumann. In the end, the Ministry decided not to proceed with the survey it originally planned to remedy the gap in knowledge in respect of this factor. One of the expert members of the review panel, Professor Stärk, was asked to peer review the Ministry's adaptation of the Neumann/Morris model. The Ministry's

reworked model, with the variables it determined, returned a mean result of one introduction into a pig farm every 4,635 years.

[40] On 1 September 2010, the Director-General released what was described as his "decision" on the findings and recommendations of the review panel.[48] The decision was in the form of an advisory report from the chief technical officer, setting out the background and ending with 10 recommendations on which the Director-General indicated that he either accepted or declined, or noted, each recommendation by striking out the inapplicable outcome and dating and signing his name at the end of the document.

The decision of the Director-General of 30 August 2010

[41] The advice given by the chief technical officer was that the review panel's expectation that the further work it recommended could be carried out in six to nine months "indicates to me that the intent of the [review panel] is for additional work to be undertaken to modify or support the conclusions in the underlying risk analysis and the resulting risk management measures in the pork import health standards, rather than for [the Ministry] to begin the process anew".

[42] The chief technical officer's recommendation on the approach to be followed, accepted by the Director-General, was that in deciding whether to accept and act "immediately" on any recommendation, the Director-General should apply a standard of "materiality" to the statutory objective of "effective management of the risks associated with the importation of risk goods"[49]:

> In this instance, it means the degree to which a particular recommendation contributes to determining the effectiveness of available risk management measures for importation of pork. In some cases, a recommendation may be material to risk management in a general sense but decisions on whether to accept the recommendation and how best to implement it need not be taken prior to making a decision on issuing import health standards for pork.

[43] As a result of this recommendation, the Director-General agreed on the further recommendation of the chief technical officer that all the review panel's "process-related recommendations" could be passed on to a general review and did

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48 This decision was made on 30 August 2010 and released on 1 September 2010.

49 Biosecurity Act 1993, s 16(a).

not need to be accepted in relation to the management measures for imported pig meat. Some of the recommendations (especially as to monitoring and management of risks after importation) could only be carried out "if import health standards for pork take effect and trade commences" but "could be part of a package of risk management measures".

[44] In response to the recommendations for further data collection and analysis, the chief technical officer advised that there were a "wide range of possibilities, from carrying out no further work to beginning the import risk analysis process anew". The chief technical director did not recommend starting again:

> [The Ministry] could choose to revisit the entire process of carrying out a new import risk analysis and subsequent development of draft import health standards, with attendant public consultations. Indeed, [the Board] has already called for this to occur. Given that [the Ministry] has spent the past five years closely studying the risks associated with pork imports, it is not clear to me that a further round of analysis and consultation would justify the resources required. Moreover, the six-to-nine month timetable suggested by the Panel for [the Ministry] to respond to their report indicates this option was not what they intended.

[45] The chief technical officer commented that the carrying out of further research and modelling and the updating of the existing risk analysis as recommended by the review panel could be time-consuming and have significant resource implications. One option was to issue the import health standards immediately on the basis that further investigation was unnecessary. The chief technical officer suggested that it was necessary for the Director-General to:

> decide how much, if any, additional activity you want [the Ministry] to undertake before I provide you with final advice about the effective management of the risks associated with pork importation.

[46] It is not stated explicitly but it necessarily emerges from the paper and its recommendations that in effect the Director-General decided that further work before he could issuing the import health standards following further recommendation of the chief technical officer was necessary only in two respects. First, a quantitative model of the risk of a PRRS incursion was to be developed by the Ministry, using any recently published relevant material, and then reviewed by independent specialists, with key stakeholders being given four weeks to comment on the design

of the model. Secondly, an expert working group was to be set up to review input variables for the quantitative modelling, with sensitivity analysis being used where necessary for inputs in the quantitative modelling. The Director-General noted that the Ministry did not propose to investigate further the extent of trimming of raw pork to test the hypothesis on which the 3 kg cut was based. Rather, "a range of values and test assumptions" would be modelled through the expert working group. Stakeholders were to be invited to nominate experts to have input into both the modelling design and the input variables.

[47] Updated information readily obtainable would be used, but further research work suggested in relation to PRRS by the review panel would be undertaken by the Ministry for the purposes of assessing "whether risk management measures specified in the provisional import health standards are effective". The chief technical officer recommended that the Director-General note that the "output of the model, in predicted frequency of outbreaks, will largely inform my future recommendations to you on the effectiveness of measures to manage the risk of PRRS introduction". That is to say, the model output was acknowledged to be critical to the chief technical officer's recommendation under s 22(1).

[48] The effect of this decision seems to me to be that the Director-General took the view that the outstanding question before introduction of the import health standards was modelling the risk of introduction of the virus. Two pieces of work only were required: finalising the structure of the model, and determining the input variables (including by sensitivity analysis in respect of the pork trimmings information gap). Other risks in managing the virus, should it be introduced, and the information needed to assess the risks and develop management strategies in that event (such as in relation to the spread of the virus if introduced or the effect on the virus of chilling pigmeat), would be the subject of ongoing work after introduction of the import health standard and, if necessary, lead to adjustment of standards. The criticisms the review panel had made of the Ministry's processes were left to be picked up in a more general review of border controls.

The expert working group

[49] Dr Neumann was nominated by the Board to participate in the expert working group comprising 11 members. Also in the group were two experts from EpiX Analytics LLC, Dr Zagmutt and Dr Groenendaal, appointed by the Ministry. The Ministry's model, which it had continued to work on in adaptation of the Neumann model, was considered by the expert working group. It resulted in no agreement. Some of the experts considered the model was fundamentally flawed and required reconstruction. Internal Ministry documents of the time indicated that the Ministry was by then bracing itself for legal challenge.

[50] Dr Neumann himself produced a revised model which represented household and retail food sector waste fed to small commercial and non-commercial herds. The retail waste stream had not before been modelled. Of particular significance was that it included discard of whole cuts of meat (from freezer or cold store failures or sell by dates on packaging). Instead of the Ministry's mean prediction of one incursion per 4,635 years, this model predicted a median of 9.8 PRRS introductions per year, with a mean result of 16 introductions per year. This model was produced by Dr Neumann too late for the expert working group to consider it.

[51] The expert working group reported to the Ministry on 29 October 2010. Its report was released at the beginning of November.

The Zagmutt-Groenendaal model produced by EpiX Anaytics

[52] With the expert working group unable to come to an agreement, the Ministry asked Dr Zagmutt and Dr Groenendaal of EpiX Analytics (who had been members of the expert working group) to review the latest Neumann model. They produced a report critical of the model, which they said threw up some impossible results and contained at least one insupportable assumption. The Zagmutt-Groenendaal model, received by the Ministry on 14 December 2010, produced a much lower risk assessment than Dr Neumann's. It predicted one outbreak on average every 1,227 years.

[53] The Zagmutt-Groenendaal model produced by EpiX Analytics was not released by the Ministry. The Board, which had learned of the report and risk model when it was mentioned in an email, unsuccessfully sought disclosure of it in February 2011. Its request was declined by the Ministry on 24 March.

[54] Before then, the chief technical officer had submitted recommendations to the Director-General for decisions to be taken under s 22A(3) of the Biosecurity Act and which also recommended that the Director-General issue under s 22 of the Act the final import health standards issued as provisional in April 2009, in reliance on the Zagmutt-Groenendaal model.

[55] The decision of the Director-General dated 10 April 2011 was released on 13 April 2011. On the same date, the Ministry released the EpiX Analytics report dated 14 December 2010 containing the Zagmutt-Groenendaal model for risk adopted by the Director-General in his s 22A determination. On the same date, also, the Director-General issued the new import health standard for pig meat, dated 18 March 2011 which adopted in final form under s 22(1) the standard provisionally made in April 2009, in the form of the draft released for consultation in November 2007. The Ministry's earlier reliance on qualitative analysis in setting the standards was said to have been supported by the quantitative analysis carried out by EpiX Analytics in the Zagmutt-Groenendaal model.

The 10 April 2011 decision of the Director-General

[56] On 13 April the Director-General issued what was described as a "decision in accordance with Section 22A(3) of the Biosecurity Act 1993". The report recited the history of the April 2009 provisional import health standards and the request from the Board which led to the report of the review panel in March 2010. The decision recites that, following the report of the review panel, "the (then) Director General agreed to a programme of work in response to the report" (referencing the chief technical officer's advice) and that the "work programme has now been completed":[50]

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[50] Footnotes omitted.

> The development of the quantitative risk model has been a long process involving several levels of peer review, including through the EWG process, and various structural changes to incorporate recommendations. The model described in the report of the expert consultants, EpiX Analytics LLC (an independent consultancy specialised in quantitative risk analysis), is accepted by [the Ministry] as "fit for purpose" to support a decision on whether import health standards issued under the Biosecurity Act section 22 provide for effective management of biosecurity risk. The model supports the conclusions of [the Ministry]'s earlier qualitative risk analysis in that respect. The model reports a mean of 0.0038 PRRS virus primary introductions per year if the importation of pig meat in the proposed consumer-ready form were permitted. This model output can be considered to be equivalent to an average of 1,227 years between outbreaks, given the current conditions and parameters assumed in the model. The expert consultants EpiX Analytics have offered their view that the model provides a conservative estimate of risk, in that the selection of parameters for severable variables are likely to over-state the risk.

[57] The decision identifies the "matter in dispute" as one that "can be described at two levels":

> *Overall*, the matter in dispute is whether [the Ministry] has taken appropriate account of the available science in determining that the provisional import health standards provide for effective management of biosecurity risk, considering the legal obligations of Section 22(5) of the Biosecurity Act 1993.
>
> *In detail*, the matters in dispute are effectively summarised as each of the individual matters in the terms of reference [the Ministry] established for the [review panel]. These are referred to in the terms of reference under the following headings:
>
> 1. Scope of the standards
> 2. Virus levels in imported meat
> 3. Impact of changes in volume of trade
> 4. Likelihood of infection
> 5. Knowledge of New Zealand industry, and consequent spread risk
> 6. Relevance of quantitative models
> 7. Overall assessment of risk

[58] In answer to the "overall" matter in dispute, the Director-General decided, for reasons which are contained in "two technical briefings" which are annexed to the decision:

- The final import health standards, and [the Ministry]'s process to develop them (including the additional work undertaken in response to the [review panel]) has taken appropriate account of the available science, and will provide for effective management of biosecurity risks, considering the legal obligations under Section 22(5) of the Biosecurity Act.

- A minor amendment to the specification of the requirements in relation to pH-cured pork in the final import health standards is appropriate to take account of the published science on viral stability, while effectively managing biosecurity risk and remaining aligned with manufacturing norms, thereby meeting the principle of being least-trade restrictive in accordance with the [SPS Agreement].

[59] Each of the "detailed matters in dispute" was then addressed in the remainder of the document. The decisions accorded with the approach taken in the 30 August paper. The recommendations directed to the processes followed by the Ministry were treated as not raising "specific matters requiring a decision in relation to the pork import health standards" and were referred to a more general review, the Border Change Programme, being conducted within the Ministry.

[60] The review panel had recommended that more recent scientific knowledge bearing on meat infectiousness should be used to review the risk assessment it had earlier carried out. The Director-General's response referred to the 30 August response to the review panel in which it had been pointed out that the risk assessment had not relied on diagnostic tests "but instead is based on direct estimation through observational studies". The Ministry had not considered that technological developments in diagnostic testing would "necessarily assist in determining effective biosecurity measures to manage the risk posed by PRRS at this time". It considered that infectiousness and virus concentration could be addressed in quantitative modelling (including sensitivity analysis), which could draw on the findings of other risk assessment bodies. Further empirical studies were unlikely to greatly add to existing knowledge and the time and cost in carrying them out were not justified.

[61] The quantitative modelling on the risk of a PRRS incursion was to be the principal tool for addressing the concerns expressed by the review panel. It would draw on any relevant recently-published material and would "incorporate dose-response data highlighted by the [review panel]" and "investigate the effect of meat

treatments such as pH and age curing on PRRS virus survival". While studies to measure trimming and disposal of fresh pork by New Zealand consumers would not be carried out, modelling would use "a range of values and test assumptions through the expert working group". The decision given by the Director-General on 13 April 2011 confirmed the approach indicated in the August response and concluded that the updated quantitative risk assessment conducted by EpiX Analytics had taken appropriate account of the limitations of the diagnostic tests in determining the proportion of imported pork likely to contain an infectious amount of the PRRS virus. The decision concluded that the EpiX risk assessment had taken appropriate account of the available science relevant to the likelihood of meat being infectious, the level or virus likely to be present in imported pig meat and the infectious dose of the PRRS virus. It further concluded that development of the EpiX risk assessment had treated uncertainty appropriately, and had used scenario and sensitivity analysis to look at the effect of different parameterisation options and the influence of variables and their parameters on the model output.

[62] The first decision turned on the key variable "*Contamination_P*". It had been drawn by EpiX Analytics from a 2004 study. The expert working group had concluded that the variable drawn from the same study used in the model based on Dr Neumann's original work was wrong. The Director-General accepted that EpiX Analytics had employed a "more methodologically correct" means of using the data from the study and had taken into account "the limitations of the current scientific evidence used to derive the *Contamination_P* variable".

> The innovation is to combine the two sets of data as two beta distributions multiplied together, using the Magar and Larochelle (2004) empirical evidence rather than expert estimates. This avoids the need to specifically set a lower bound estimate, as required when the Pert distribution was used in both the original Neumann *et al* (2007) model and the revised [Ministry] model.

[63] The second decision turned on the key variable in step four of the quantitative model, which arrived at "an estimate for the variable *Scrap_Viral_Concentration*". The Director-General expressed satisfaction that the final model incorporated "a comprehensive and robust process to parameterise the key variable *Peak_Virus_Concentration_At_Slaughter*, following the [expert working group] process to identify potentially relevant publications and the [EpiX Analytics]

application of meta-analysis techniques to this data". EpiX Analytics had "reviewed the model's use of variables to represent the chain of events after slaughter that affect eventual viral concentration in meat", and had rejected any suggestion of double counting. The parameters selected had been based on a risk assessment reported by the European Food Safety Authority (EFSA)[51] and had used recently published studies on viral survival.

[64] The third decision was based on an innovation in the Ministry's revision of the Neumann model, incorporating a 2005 study on infectious dose. The expert working group had agreed this was acceptable use of the data. The Director-General noted that "[a]n issue arises, however, with the extrapolation to low doses from the Hermann *et al* (2005) data which is important as the number of trials increases (trials being feeding events i.e. a scrap of uncooked imported pig meat being fed to a pig in New Zealand)":

> This became particularly relevant when other model changes were introduced as a result of the [expert working group]. The expert consultants EpiX Analytics demonstrate the effect of different model fitting options at doses below that which the Hermann *et al* (2005) study demonstrated did not achieve transmission. These different statistical methods result in curves that vary significantly in shape as the probability approaches zero. The experts conclude that the Logistic dose-response model reported by Hermann *et al* (2005) is not appropriate when making low dose extrapolations beyond the experimental data (as is required in this risk assessment model). They conclude that alternative models widely used in food-safety modelling are more appropriate, and have used a Beta-Poisson model in their report and final model.

[65] The fourth decision was justified on the basis that EpiX Analytics had emphasised that "the overall model structure reflects the objective of estimating likelihood incorporating uncertainty around the mean, rather than the variability across the system":

> Throughout the model the expert consultants [EpiX Analytics] have checked to ensure parameters use the available data appropriately in this respect. Their reports to the [expert working group] and accompanying their final revised model describe the scenario and sensitivity analyses they have undertaken.

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[51] The use of the EFSA report was a matter of dispute on the evidence: see below at [73].

The contestability of the EpiX Analytics report

[66] The decision to issue the import health standards on 13 April was a matter for the Director-General under s 22(1), provided that he acted reasonably and in accordance with the legislation. (Only the second ground of challenge is put forward in these proceedings, which are not concerned with substantive unreasonableness.) Since, however, a strand of the reasoning in the Courts below has been that the lengthy process of evaluation undertaken was exhaustive, it is relevant background when considering whether the arguments of the appellants turn (as the majority in the Court of Appeal thought) on insistence on form over substance, that the EpiX Analytics report is regarded as contestable by a number of experts who provided evidence in the proceedings.

[67] The Director-General had already acknowledged in setting the standard that the risk of incursion of the virus through feeding contaminated raw meat to pigs in New Zealand was not negligible. That was substantiated by the evidence of Professor John Wilesmith that, in the United Kingdom, a foot-and-mouth disease virus outbreak in 2001 and a swine fever outbreak of 2000 had arisen from ingestion by pigs of imported infected pig meat that had been disposed of as waste.

[68] It is quite clear that the EpiX Analytics report was essential to the adoption of the standards. The review panel had found that the qualitative analysis on which the provisional standards were set was inadequate and that it contained significant gaps in knowledge, in relation to the effectiveness of the key risk management strategy of restricting sale of imported raw pig meat to cuts of less than 3 kg.

[69] As the Director-General's decision of 10 April 2011 indicated, the variables and the sensitivity analysis used by EpiX were critical to the predictions on which the Director-General concluded that the standards could be issued, in conformity with s 22(1), for the "effective management of risks associated with the importation" of raw pig meat. The model was itself highly sensitive to the assumptions adopted.

[70] Criticisms of the EpiX Analytics model were made in the evidence given by four experts. They were Dr Lawton (a New Zealand pig veterinarian and epidemiologist), Dr Neumann (who had been the Board's nominated member of the

review panel and a lecturer at Massey University specialising in pig medicine and epidemiology), Professor Morris (retired Professor of Animal Health at Massey University and a co-author with Dr Neumann of the first quantitative model put forward by the Board), and Professor Wilesmith (a United Kingdom veterinary epidemiology consultant first nominated by the Ministry as a member of the review panel and then nominated by Federated Farmers as a member of the expert working group).

[71] Dr Lawton gave evidence that in New Zealand many pig herds are fed commercial, supermarket, and household food waste and meat scraps, despite the regulations. He pointed to studies which indicate high transmission rates of the PRRS virus from feeding infected meat to "naïve pigs" (as the New Zealand pig population can be expected to be) and from which it would be readily transmitted to other pigs. He considered that the prediction of incursion of the virus was a result of the inclusion of suspect risk reduction factors and that the model was too optimistic in the variables used for detection since he was of the view that infection was more likely initially in relation to small producers who were less likely to identify the existence of the virus.

[72] Dr Neumann criticised the EpiX report for its treatment of infectiousness, the "novel" mitigation strategy of limiting cuts to consumer-ready portions of less than 3 kg, as something not adopted in any other country and as supported by no evidence. He questioned the adequacy of the variables relating to transmission and the persistence (and difficulties in eradication) of infection.

[73] Dr Wilesmith expressed the opinion that the EpiX Analytics report of 14 December "did not provide an adequate scientific basis for the conclusions reached by the Director-General" and did not deal effectively with the review panel's report. He expressed concern about the treatment of import volumes (a "key driver" in import risk analysis) in the Director-General's decision as "inherently speculative" and based on outdated data of little relevance which ignored the estimates of volumes discussed by the expert group. Nor did he consider that adequate sensitivity analysis had been used in the Zagmutt-Groenendaal model. He criticised the Director-General's decision that the findings of other risk assessment groups such as

EFSA could be used to inform quantitative modelling instead of "costly and time-consuming" additional studies as inadequate to respond to the review panel's consideration and analysis which had explained why the Ministry's interpretation of and reliance on the EFSA report was wrong. He referred to other studies discussed by the expert working group but ignored in the Zagmutt-Groenendaal model. He considered the model "poorly conceived and executed" and said that the report contained "a number of inappropriate judgments and statements and fail[ed] to adequately deal with the range of scientific information and views presented during the expert working group process". Professor Wilesmith's conclusion was that the import risk analysis undertaken by the Ministry did "not provide a sound scientific basis for the Director-General to justify the import health standard approved in April 2011".

[74] Professor Morris provided the opinion that the Ministry had been wrong not to undertake a hazard analysis (as had been undertaken in Australia) and that it had "fail[ed] to adequately interpret and take account of the scientific evidence". The modelling it had undertaken (which had been built on in the Zagmutt-Groenendaal model) was criticised for not looking at virus concentration, a direct and influential factor in assessing risk. He considered that the Zagmutt-Groenendaal model had failed adequately to incorporate the scientific literature available and had used historic data which "artificially lowers the risk estimate". He considered that the 3 kg figure used was unsubstantiated and based on unscientific subjective assessment and its continued use was contrary to the review panel's recommendations. Nor had the Ministry substantiated (including by acting on the review panel's recommendations of data collection) what the review panel had considered "overly optimistic" assumptions of virus movement. Professor Morris was critical of the Zagmutt-Groenendaal model and considered that it provided a "very substantial underestimate of the risk of a PRRS incursion in New Zealand under the new import health standards". He identified the three most influential variables in the model as being: the amount of imported pork; the proportion of imported pork sold as consumer-ready cuts; and viral persistence after slaughter (how long the virus would remain contagious within the meat). He considered that the values used in the model on these key factors were based on inadequate science. Despite the sensitivity of the model to these assumptions, he considered it undertook insufficient sensitivity

analysis. Correction of these deficiencies could dramatically alter the prediction of incursion to as low as under five years.

[75] These opinions were countered by the experts and officials who provided affidavits for the Ministry. The authors of the EpiX Analytics report defended their methodology and their decision not to use some of the assessments suggested by the witnesses for the Board. Other members of the expert working group explained that opinions had become polarised in the group and that detachment had become questionable, including from those who gave evidence for the Board.

[76] As already indicated, the purpose in referring to the evidence put forward by the Board is not to question the view taken on the merits by the Ministry or the Director-General. It is to indicate that some substantial issues have been raised which underscore the need for proper process in accordance with the legislation.

Compliance with the legislation

[77] In the High Court, Williams J held that the process adopted following the report of the review panel miscarried. The statement in the terms of reference and the advice paper "of an overall issue",[52] which invoked the s 22 determination, and the reference to s 22(5) in the 10 April 2011 decision indicated an overstepping of the "disciplined line required to be maintained by s 22A"[53] and amounted to "an attempt to step back and recast the debate" on the part of the Ministry.[54] The Judge noted that s 22A was "designed to provide a process of scientific inquiry into issues raised by a stakeholder"[55] and that it was those issues which should be the focus. Despite this error in approach, the Judge concluded that no harm was done by "what, in the end, should be seen as a technical misstep" because the Director-General had in fact addressed all the issues raised by the Board.[56] The reference to s 22(5) in the s 22A decision was "not fatal on a first run at these processes" because the result of the final s 22A was "completely science focussed".[57]

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52 *New Zealand Pork Industry Board v Director-General of Ministry of Agriculture and Forestry* [2012] NZHC 888 at [130].
53 At [130].
54 At [130].
55 At [130].
56 At [131].
57 At [132].

[78] On appeal, the majority in the Court of Appeal considered that, since the purpose of the procedure under s 22A was ultimately to inform the Director-General's determination under s 22, the two statutory procedures were linked.[58] Section 22A was concerned to establish whether the Ministry had sufficiently considered the scientific evidence when developing an import health standard. It was of no assistance to the Director-General simply to determine who was "right or wrong" in a matter of dispute[59] and the determination of each of the nine issues referred to the Board "would be a pointless exercise".[60] The establishment of a review panel could not derail the statutory process under s 22 for the development of an import health standard. The s 22A review panel process was, rather, "complementary to the broader task of issuing an [import health standard]".[61] On this view, the issue in dispute was rightly set out in [15] of the terms of reference (which invoked 22A(1)) as being to assess "whether [the Ministry's] treatment of the issues, given all the evidence, was reasonably open to it, and whether there is a reasonable chain of logic linking the science to the provisional import health standards".[62] The questions posed in the terms of reference were, rather, "particulars".[63]

[79] The majority in the Court of Appeal took the view that the review panel's review was one step only in the process of developing and issuing an import health standard:

> [60] The statutory responsibility for developing and implementing the [import health standards] under s 22 remains with the Director-General throughout. The Panel's participation did not stop the clock or oblige the Director-General to restart the process. In our judgment, the process adopted by the Director-General here of considering the Panel's findings and taking account of and implementing its recommendations within the overall framework of deciding to issue the [import health standards] accorded with the statutory requirements.

[80] In this Court, the Board continued to maintain that the Director-General had failed to fulfil the obligation under s 22A "as soon as reasonably practicable" to

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58 *New Zealand Pork Board* (CA), above n 10, at [53].
59 At [53].
60 At [54].
61 At [53].
62 At [56].
63 At [57].

"determine the issue in dispute", which it characterised as contained in the nine questions treated by the Court of Appeal majority as "particulars". Mr Cooke argues that the Director-General asked himself the wrong question when in the 10 April 2011 decision he described and answered the "overall" matter in dispute as being whether the Ministry had "taken appropriate account of the available science in determining that the provisional import health standards provide for effective management of biosecurity risk, considering the legal obligations of Section 22(5) of the Biosecurity Act 1993". That, he argued, was the question for the Director-General under s 22 of the Act, not the matter in dispute under s 22A, which required the Director-General in the present case to decide all matters identified in the terms of reference. Nor had the Director-General discharged his obligation to determine the matter in dispute "as soon as reasonably practicable".

[81] The sequence and effect of the decisions taken by the Director-General has been complicated by the fact that two purported s 22A decisions were given. In the Courts below it seems to have been accepted, following the arguments of counsel, that the s 22A decision was that given on 13 April 2011. (In the Court of Appeal, the majority indicated that either decision complied with the statutory process.) In this Court, the majority consider that both "decisions", that of 30 August 2010 and that of 10 April 2011 are to be read together as comprising the s 22A decision. I take a different view, although ultimately I do not think it greatly matters whether the 30 August 2010 decision was augmented by the 10 April 2011 decision. The appeal turns rather, it seems to me, on whether s 22 has been complied with.

[82] I consider that the 30 August 2010 decision adequately discharged the Director-General's obligation under s 22A(3). It was a determination of the dispute raised by the Board that there had been inadequate regard to the scientific evidence in developing the provisional standards, after taking into account the findings and recommendations of the independent review panel. And I think it adequately set out the reasons why the Director-General accepted that the science used had not been adequate in relation to risk assessment and that further work was therefore required. I do not however consider that the obligations under s 22 were properly discharged.

[83] In his August 2010 advice on the approach to be followed, the chief technical officer had indicated that the Director-General could decide, on the basis of materiality to the effectiveness of available risk management, that the recommendations need not be implemented before making a decision on issuing an import health standard. The Director-General did not adopt that course in relation to the risk assessment. Nor however did he decide to start the entire process of risk assessment all over again, with a view to publishing a further draft import health standard. He decided, contrary to the recommendation of the review panel, that further empirical studies of disposal of waste pork in New Zealand should not be carried out (both for reasons of cost and time and because the resulting information was unlikely to be particularly robust) and that risks in managing the virus, should it be introduced, could be the subject of ongoing work which need not delay the introduction of the import health standard if the risk assessment for incursion of the virus was acceptably low. Whether these decisions were reasonably open to the Director-General does not arise on the appeal.

[84] As advised by the chief technical officer, and acting in accordance with the views of the review panel, the Director-General determined that additional modelling for the risk of introduction of the virus was necessary. That work entailed both developing the structure of the model (on the basis of the work already undertaken by Dr Neumann and by the Ministry) and determining the input variables, including the sensitivity analysis required to recognise the gaps in empirical and scientific knowledge. (The expert working group was put together to provide the Ministry with help with the variables and this work was ultimately undertaken by EpiX Analytics.)

[85] The decision not to fill the gaps in knowledge by further research meant that the quantitative modelling would be determinative of whether the import standard would effectively manage the risk associated with importation of raw pork. That was acknowledged by the chief technical officer when he advised the Director-General on 30 August 2010 that the "output of the model, in predicted frequency of outbreaks, will largely inform my future recommendations to you on the effectiveness of measures to manage the risk of PRRS introduction". (Whether an assessment based on the modelling to be undertaken would properly have discharged

the obligation of the chief technical officer under s 22(5)(b) to have regard to "the nature and possible effect on people, the New Zealand environment, and the New Zealand economy" is not a matter that arises for consideration on the appeal.)

[86] The chief technical officer was obliged under s 22(1) to make a recommendation on the import health standard to be adopted once the s 22A determination had been that further work was required, as the scheme of the legislation made clear, and as is now explicitly provided for in the new s 24A. That position had been clearly appreciated by the chief technical officer in his 30 August 2010 advice. I am of the view that the process envisaged by the legislation miscarried because the implications of the Director-General's decision of 30 August 2010, accepting that the science to date had been inadequate, seem to have been lost sight of in the rolling maul that then ensued between the experts. Once the additional work had been done, the chief technical officer still had to make his s 22(1) recommendation.

[87] Under s 22(6) of the Act, the chief technical officer could not make such a recommendation without consultation, unless what was proposed was not the issue of a standard (as here) but a minor amendment to a standard. Under s 22(7) such consultation could take place either on the standard "or on a document that analyses or assesses the risks associated with the goods or class of goods to which the goods belong". In the present case, it was the risk analysis provided by the quantitative modelling that was critical and on which consultation was required by the legislation before a recommendation could be made by the chief technical officer and a valid standard issued.

[88] There was no consultation on the EpiX Analytics report of 14 December 2010. The expert working group had concluded in October 2010 without opportunity to consider Dr Neumann's revised model. The EpiX Analytics model was the result of additional work it undertook between October and December. The adjustments it made to the Neumann revised model, the values it incorporated into the model, and the sensitivity analysis it undertook were not the subject of consultation or indeed disclosure until the EpiX Analytics report was released after

the import health standards were adopted in April 2011. This failure to consult or disclose included three key changes:

- The "innovation" acknowledged by the chief technical officer in relation to the "key variable" *Contamination_P* (referred to above at [62]).

- The process of setting the parameters in relation to the key variable *Scrap_Viral_Concentration* (in part drawing on the EFSA assessment criticised by the review panel), based on EpiX Analytics' new review of variables and new meta-analysis (referred to above at [63]).

- EpiX Analytics' new extrapolation to low doses from the study earlier considered by the expert working group for the variable on infectious dose and the use of alternative models (see above at [64]).

[89] I consider that in a matter of such importance as the issuing of an import health standard against the background of acknowledged risk, the formal statutory processes must be properly observed. It cannot be assumed that consultation would not have produced information or perspectives valuable to the recommendation of the chief technical officer or to the decision the Director-General was ultimately required to make. It is insufficient that the variables may have been discussed in the expert working group and that opportunity for input was available there to the Board through its nominee. It is the model as finalised that was critical; it is the model's combination of the variables which should have been the subject of consultation.

[90] The departures from the process envisaged by the legislation cannot be said to be immaterial. The sensitivity of the model is acknowledged. The absence of adequate empirical information or scientific knowledge to put into the model on the key variables (particularly against the background of a decision that attempting to remedy the deficiency would not be undertaken for reasons of time and cost) heightened reliance on the model and made the effective management of risk particularly vulnerable to error in the modelling. In effect, the key assumption on which the provisional standard was based (the 3 kg restriction) was not verified on any other basis. The expert opinions filed by the appellants as to possible

deficiencies in the sensitivity assessments and the scientific literature they identify which was not used in the model suggest caution in ready assumptions that the process has been exhaustive and that further consultation will not produce better outcomes. A change in the predictions might well affect not only the overall conclusion on the risk of incursion but the appropriateness of the view that further assessment of the management of the risk of spread can be properly left to further development.

[91] For these reasons, which are similar to those given by White J in his dissenting opinion in the Court of Appeal, I would allow the appeal.

McGRATH, WILLIAM YOUNG, GLAZEBROOK AND ARNOLD JJ

(Given by Arnold J)

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Import health standards for pork challenged

[92] Porcine Reproductive and Respiratory Syndrome (PRRS) is a viral disease affecting pigs. It is highly contagious and is spread principally by contact between live pigs or through pig semen. Pigs can also become infected, however, by eating raw meat from infected pig carcasses. There are relatively few countries in the world which are free of PRRS. New Zealand is one of them, as is Australia. Countries that are PRRS-infected include Canada, countries in the European Union, and the United States of America, in which substantial quantities of pork are produced. PRRS can be eradicated from a country's pig herds by the application of appropriate biosecurity measures, as has occurred in Chile and Sweden. PRRS does not affect any other species and has no implications for human health. The virus is destroyed by processes such as cooking and curing, so that PRRS-infected pork meat can safely be eaten by humans.

[93] Prior to August 2001, when there were no prohibitions against it, New Zealand imported substantial quantities of raw pork from PRRS-infected countries without any outbreak of the PRRS in the New Zealand pig population.[64] However, in August 2001, in light of new research indicating that pigs could become infected through eating raw meat from infected pig carcasses, the respondent, the Director-General of the Ministry for Primary Industries,[65] after consultation with the appellant, the New Zealand Pork Industry Board (NZ Pork), promulgated provisional import health standards under s 22 of the Biosecurity Act 1993 (the Act).[66] The provisional import health standards required all imports of pork from countries known to be infected with PRRS to be cooked or treated; the importation of raw pork was prohibited.

[94] Following that, there was a lengthy period of investigation and consultation, including a review by an independent review panel (review panel) under s 22A of the

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64 *New Zealand Pork Industry Board v Director-General of Ministry of Agriculture and Forestry* [2013] NZCA 65 (Harrison, Stevens and White JJ) [*New Zealand Pork Industry Board* (CA)] at [5] per Harrison and Stevens JJ.

65 Formerly the Ministry of Agriculture and Forestry.

66 The sections particularly at issue in this case, ss 22 and 22A, were repealed and substituted from 18 September 2012 by s 20 of the Biosecurity Law Reform Act 2012. The equivalent provisions are now in ss 22, 23 and 24 of the Biosecurity Act 1993. (We note that other related provisions were added by s 20 of the Biosecurity Law Reform Act: see ss 24A–D of the Biosecurity Act.) We will refer throughout to the sections as they stood at the relevant time.

Act. Ultimately, in April 2011, the Director-General issued import health standards permitting the importation of raw pork from PRRS-infected countries provided that the meat is pre-packaged in consumer-ready cuts of three kilograms or less and specified tissues have been removed.[67] NZ Pork then issued judicial review proceedings challenging the lawfulness of the Director-General's decision. NZ Pork claimed that the Director-General had not properly followed the statutory process set out in s 22A in relation to the independent review and that a statutory obligation to consult had been breached. NZ Pork was unsuccessful before Williams J in the High Court[68] and on appeal to the Court of Appeal, although that Court was divided.[69] This Court granted leave to appeal on the following grounds:[70]

> (a) whether the Court of Appeal's interpretation of ss 22 and 22A of the Biosecurity Act 1993 was correct;
>
> (b) whether the Director-General correctly applied the requirements of ss 22 and 22A following the report of the Independent Review Panel.

Development of the import health standards

August 2001: Director-General promulgates provisional import health standards

[95] The provisional import health standards issued in August 2001 were a precautionary measure, introduced in response to the new research indicating that pigs could be infected with PRRS through the consumption of raw pig meat. Consistently with New Zealand's international obligations,[71] following the introduction of the provisional standards, the Ministry of Agriculture and Forestry (the Ministry) began to develop an import risk analysis designed to estimate the likelihood (expressed in terms of frequency) of PRRS being introduced to pigs in New Zealand if the importation of raw pork from PRRS-infected countries were to be permitted. Before that work was completed, the Biosecurity (Meat and Food Waste for Pigs) Regulations 2005 were promulgated, reg 5 of which prohibited the

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67 The importation of minced or ground pig meat and pig heads and necks is prohibited.

68 *New Zealand Pork Industry Board v Director-General of Ministry of Agriculture and Forestry* [2012] NZHC 888 [*New Zealand Pork Industry Board* (HC)].

69 *New Zealand Pork Industry Board* (CA), above n 64. The majority comprised Harrison and Stevens JJ; White J dissented.

70 *New Zealand Pork Industry Board v Director-General of Ministry of Agriculture and Forestry* [2013] NZSC 50.

71 See the discussion at [113]–[119] below.

feeding of raw meat to pigs.[72] Although this prohibition remains in force, the evidence suggests that its enforcement has not been fully effective and that food waste including raw meat may be fed to pigs, particularly in non-commercial settings such as so-called backyard operations, which are common in New Zealand.[73]

July 2006: Ministry issues import risk analysis for consultation

[96] In July 2006 the Ministry released its import risk analysis for consultation under s 22(6) of the Act.[74] The analysis, which was largely qualitative rather than quantitative in nature,[75] concluded:

> 1. There is a low likelihood that chilled or frozen pig meat from a country with endemic PRRS will harbour the virus when imported into New Zealand.
>
> 2. Since cooking inactivates the PRRS virus, and since pigs are the only species susceptible to this organism, effective exposure would require the feeding of uncooked pig meat to pigs in New Zealand. Although scraps may be generated from imported pig meat at several points during its preparation for human consumption, the feeding of raw meat to pigs is illegal under the 2005 garbage feeding regulations. It is concluded that an exposure pathway would exist only on pig farms that were not complying with the garbage feeding regulations.
>
> 3. If pig farms in this country did become infected with PRRS through the illegal feeding of uncooked imported pig meat, the likelihood of spread to other pig farms would be low as long as standard biosecurity practices were observed.
>
> 4. If PRRS virus were introduced into New Zealand, the consequences would be significant on affected farms, particularly in breeding units.

The Ministry considered that the risk of PRRS in imported meat was "non-negligible" and recommended various "sanitary measures", including allowing the importation of raw pork from PRRS-infected countries only in the form of

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72 The prohibition relates to "untreated" meat, which effectively means meat that has not been heated to 100 degrees Celsius for at least an hour or treated by some other prescribed method: see Biosecurity (Meat and Food Waste for Pigs) Regulations 2005, reg 4: definitions of "untreated meat" and "treated".

73 See *New Zealand Pork Industry Board* (HC), above n 68, at [18].

74 Noel Murray and Howard Pharo *Import Risk Analysis: Porcine Reproductive and Respiratory Syndrome (PRRS) Virus in Pig Meat* (Biosecurity New Zealand and Ministry of Agriculture and Forestry, 25 July 2006) [2006 *Import Risk Analysis*].

75 These terms are explained at [136] below.

"consumer-ready, high value cuts".[76] The theory was that these cuts would generate minimal waste on the part of consumers, thus reducing the possibility of raw pig meat finding its way into pig swill.[77]

2007: The Neumann/Morris model

[97] The Ministry's import risk analysis was peer-reviewed by eight international experts.[78] In addition, various organisations were consulted, including NZ Pork. NZ Pork retained two New Zealand-based experts, Dr Neumann and Professor Morris, to assist. They carried out a quantitative assessment of the risk of the introduction to New Zealand of PRRS if raw pork imports were permitted, as proposed, and produced a risk model (the Neumann/Morris model). The Neumann/Morris model predicted an average of 4.3 outbreaks of PRRS per year as a result of exposure to the PRRS virus through feeding pigs food scraps including raw pig meat.

2007–2009: Draft and provisional import health standards issued

[98] In November 2007, the Ministry released draft import health standards for pig meat for consultation. These permitted the importation of "ready-to-cook, high value cuts of pig meat" from PRRS-infected countries. Following a period of consultation, the Director-General issued provisional import health standards in April 2009, again allowing the importation of consumer-ready pork cuts (essentially, pre-packaged cuts of three kilograms or less with certain tissues removed) from the European Union, Canada, the United States and the Sonora State of Mexico. On 28 May 2009, NZ Pork formally requested that the Director-General set up an independent review panel under s 22A of the Act to consider whether the Ministry had had sufficient regard to the scientific concerns which NZ Pork had raised.

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[76] These cuts could be prepared overseas or in specially designated transitional facilities in New Zealand.

[77] 2006 *Import Risk Analysis*, above n 74, at Figure 6 and [4.2.2.3].

[78] International experts were involved because there was limited expertise or research on Porcine Reproductive and Respiratory Syndrome (PRRS) in New Zealand, given that PRRS is not present in New Zealand.

2009: Review panel established

[99] The Director-General acceded to NZ Pork's request[79] and set up a review panel comprising a Queen's Counsel as Chair and three overseas experts. The terms of reference for the review panel identified nine particular issues for consideration. The review panel conducted its enquiries between November 2009 and March 2010 and reported to the Director-General, in writing, on 31 March 2010. In general terms, the review panel concluded that the Ministry had fully considered the science available in most but not all areas, and that it had applied recognised international standards for risk assessments. However, the review panel noted that in some areas there had been developments in the science and in the availability of data since the Ministry had completed its import risk assessment. Accordingly, it said, further work would be useful to ensure that any revised risk assessment took account of the current science and associated demographic and epidemiological data. Whereas the Ministry's risk assessment had been qualitative in nature, the revised assessment should adopt a quantitative approach. This quantitative analysis was seen as being complementary to the Ministry's qualitative analysis rather than replacing it. The review panel estimated that this additional work would take six to nine months to complete, depending on the resources available.

April 2010: Ministry meets stakeholders to discuss review panel's report

[100] In April 2010, the Ministry held a workshop with stakeholders, including representatives of NZ Pork, to discuss how to proceed in light of the review panel's report. The Director-General accepted that further work should be undertaken, and the Ministry began to implement various work streams. These included developing a quantitative risk assessment based on the Neumann/Morris model. In the course of this work, on 14 July 2010, Ministry personnel held a teleconference with the three scientific members of the review panel to obtain feedback on their progress with the model to date.

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[79] Pursuant to the Biosecurity (Process for Establishing Independent Review Panel) Notice 2008 (26 June 2008) 104 *New Zealand Gazette* 2765, cl 9.

September 2010: Director-General issues response to review panel's report

[101] On 1 September 2010, the Director-General issued a formal response to the review panel's report. He advised that he had decided that the Ministry should carry out further work to "guide his decision on the biosecurity risk management measures within the health import standards". The Director-General noted that a risk analysis using quantitative methodology was central to the work programme and that the Ministry would develop this, based on the Neumann/Morris model. The Director-General said that he wanted the Ministry's draft risk analysis to be peer reviewed by an independent expert. Finally, the Director-General indicated that he wished to set up an expert working group, the members of which would be given the opportunity to contribute to a further review of the quantitative risk analysis. Stakeholders such as NZ Pork would be able to nominate an expert to be part of the group.

September 2010: Ministry completes its revised risk analysis model

[102] By September 2010 the Ministry had completed its development of the quantitative risk analysis model based on the Neumann/Morris model (the Ministry's revised model). It had retained Professor Katharina Stärk of the Royal Veterinary College in the United Kingdom, who had been a member of the review panel at the nomination of NZ Pork, to peer review it. She provided a written report dated 5 September 2010, to which the Ministry responded with comments. Copies of the Ministry's revised model, Professor Stärk's commentary and the Ministry's response were provided to NZ Pork.

[103] The Ministry's revised model made some adjustments to the Neumann/Morris model. For example, the Neumann/Morris model had assumed that all pork imported into New Zealand originated from PRRS-infected countries. However, as a substantial proportion of imported pork comes from PRRS-free countries such as Australia, Finland and Sweden, the Ministry adjusted the model for that. The Ministry ran 10,000 simulations of its revised model and returned a mean result of one introduction of PRRS into a backyard herd every 4,635 years. 98 per cent of the model iterations returned results within the range of 192 to 37,572 years. The Ministry noted that sensitivity analysis had demonstrated which input

parameters could be further investigated in order to reduce the uncertainty in the output of the model.

September–November 2010: Expert working group

[104] NZ Pork nominated Dr Neumann to participate in the expert working group, and other stakeholders made their nominations. The Ministry invited two overseas experts on quantitative risk analysis to participate, Drs Zagmutt and Groenendaal of EpiX Analytics LLC. The expert working group met four times by teleconference during September and October 2010 to discuss the Ministry's revised model and provided a written report dated 7 November 2010. In the report, the Chair of the working group described the purpose of the teleconferences as follows:

> The first teleconference was devoted to ensuring all members understood the [Ministry's] model structure, and how parameters for variables had been derived. The second and third teleconferences sequentially focussed on the key issues identified by Pork [expert working group] members. Prior to the fourth teleconference the members submitted draft written reviews of the [Ministry's] report and model, and these were then discussed during the fourth teleconference, with members questioning, commenting [on] and challenging each others' reviews.

October 2010: Neumann EWG model

[105] On 29 October 2010 Dr Neumann provided a reworking of the Ministry's revised risk model to the expert working group. His reworked model (the Neumann EWG model) predicted a much higher likelihood of PRRS after the introduction of the proposed import health standards than the Ministry's revised model. However, because it was introduced after the last of the expert working group's teleconferences, the Neumann EWG model could not be analysed in any detail by the expert working group. Accordingly, the Ministry asked Drs Zagmutt and Groenendaal to provide a report on it. They noted that the Neumann EWG model produced results which, on the face of it, cast doubt on its validity. In particular, it predicted an average of almost two outbreaks of PRRS a year even when there were no imports of raw pork and, assuming that there were such imports, indicated the possibility of a negative number of outbreaks per year in some scenarios, both of which were impossibilities. It also assumed that all scraps fed by one producer were

eaten by one pig, which was inconsistent with the assumptions made in the model about the average size of non-commercial pig herds.

December 2010: EpiX model

[106] On 14 December 2010, Drs Zagmutt and Groenendaal prepared a further version of the risk model, based on the Neumann EWG model, which they submitted to the Ministry (the EpiX model). The authors said that the EpiX model did not make any fundamental changes to the structure or logic of the Neumann EWG model. Rather, it corrected what were seen to be mistakes or unjustified assumptions in it. The EpiX model predicted an average of 1,227 years between PRRS outbreaks.[80]

April 2011: Director-General issues his decision

[107] On 13 April 2011, the Director-General released what was described as his decision under s 22A(3) of the Act, dated 10 April 2011. The Director-General's decision was based on a decision paper prepared by the Ministry which noted among other things that the EpiX risk analysis supported the Ministry's conclusions in its 2006 qualitative risk assessment. The Director-General concluded that the work undertaken (including the additional work since the report of the review panel) took appropriate account of the available science and would provide for the effective management of biosecurity risks. The Director-General approved new import health standards which were materially the same as the provisional standards published in April 2009 and allowed the importation into New Zealand of pre-packaged consumer-ready cuts of three kilograms or less with tissue removed from PRRS-infected countries.

[108] NZ Pork then issued judicial review proceedings against the Director-General and the Ministry. The essential allegations were that the Director-General acted unlawfully in the way he responded to the report of the review panel and that a statutory obligation to consult had been breached.

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[80] Or a mean of 0.0038 outbreaks of PRRS each year.

The statutory background

[109] Sections 22 and 22A of the Act are the critical provisions. They are in pt 3 of the Act. Section 16 provides that the purpose of pt 3 is "to provide for the effective management of risks associated with the importation of risk goods". The parties agree that raw pork subject to the import health standard falls within the definition of "risk goods" in s 2 of the Act.

Section 22

[110] Broadly, s 22 empowers the Director-General to issue an import health standard in relation to risk goods on the recommendation of a chief technical officer, who must take certain specified matters into account before making a recommendation. Section 22 relevantly provides:

> **22 Import health standards**
>
> (1) The Director-General may, following the recommendation of a chief technical officer, issue an import health standard specifying the requirements to be met for the effective management of risks associated with the importation of risk goods before those goods may be imported, moved from a biosecurity control area or a transitional facility, or given a biosecurity clearance; and may, in a like manner, amend or revoke any import health standard so issued.
>
> …
>
> (3) Nothing in this Act obliges the Director-General to have an import health standard in force for goods of any kind or description if, in the Director-General's opinion, the requirements that could be imposed on the importation of those goods would not be sufficient to enable the purpose of this Part to be met if the importation of those goods were permitted.
>
> (4) An import health standard issued under this section may apply to goods of a certain kind or description imported from—
>
> (a) A country or countries specified in the import health standard; or
>
> (b) Countries of a kind or description specified in the import health standard; or
>
> (c) All countries; or
>
> (d) A location or locations specified in the import health standard.

> (5) When making a recommendation to the Director-General in accordance with this section, the chief technical officer must have regard to the following matters:
>
> (a) The likelihood that goods of the kind or description to be specified in the import health standard may bring organisms into New Zealand:
>
> (b) The nature and possible effect on people, the New Zealand environment, and the New Zealand economy of any organisms that goods of the kind or description specified in the import health standard may bring into New Zealand:
>
> (c) New Zealand's international obligations:
>
> (d) Such other matters as the chief technical officer considers relevant to the purpose of this Part.
>
> (6) Before making a recommendation to the Director-General on the issue or amendment of an import health standard, the chief technical officer must, unless the standard needs to be issued or amended urgently, or unless the chief technical considers that the amendment is minor, consult with those persons considered by the chief technical officer to be representative of the classes of persons having an interest in the standard.
>
> (7) The consultation may be on the import health standard or on a document that analyses or assesses the risks associated with the goods or class of goods to which the goods belong.
>
> …

[111] As will be apparent, s 22(1) repeats the language of the purpose provision, s 16, by requiring an import health standard to specify "the requirements to be met for the effective management of risks" associated with importation of risk goods. The reference to "the effective management of risks" indicates, as Ms Gwyn submitted on behalf of the respondents, that pt 3 does not require the elimination of all risk. The same point was made by the majority of the Federal Court of Australia in a decision concerning the importation of raw pig meat into Australia under the equivalent Australian legislation, the Quarantine Act 1908 (Cth):[81]

> [61] The legislation does not suggest that quarantine decisions are to be made on an assumption that every scientific fact is known about every conceivable disease or pest that might be introduced into Australia, or that such decisions are to be delayed until all such facts are discovered and accepted. On the contrary, quarantine decisions have to be made in the existing state of knowledge. Imponderables

[81] *Director of Animal and Plant Quarantine v Australian Pork Ltd* [2005] FCAFC 206, (2005) 224 ALR 103. The majority comprised Heerey and Lander JJ; Branson J dissented.

> have to be weighed and value judgments made. No specific criteria are laid down, other than the condition to be established must limit the degree of quarantine risk to one which is "acceptably low" – which necessarily assumes that there will be some risk.

[112] The matters that the chief technical officer must take into account in making a recommendation are set out in s 22(5). Sections 22(5)(a) and (b) require the making of assessments that have scientific, economic and social components. Section 22(5)(c) requires consideration of New Zealand's international obligations, which we address below. Section 22(6) imposes an obligation on the chief technical officer to consult with representatives of classes of persons having an interest in the import health standard (except in the case of urgency or a minor amendment to a standard). In terms of s 22(7), the consultation may be on the import health standard or the underlying risk assessment. As previously noted, one of the issues in this case concerns the extent of this obligation to consult.

New Zealand's international obligations

[113] Turning to New Zealand's international obligations, New Zealand is a member of the World Trade Organisation, which provides a trading system based on agreements. As such, New Zealand is a party to the World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures, which came into force in 1995 (the SPS Agreement).[82] Although New Zealand is a signatory to several international agreements affecting biosecurity, biodiversity and the environment,[83] the parties focussed on the SPS Agreement as having direct relevance to the import health standards at issue in the present case.

[114] The SPS Agreement was intended to facilitate the achievement of two objectives – the promotion of free trade and the meeting of biosecurity concerns. The essential underlying premise is that restrictions on free trade should be no greater than can be justified by valid biosecurity concerns. Critical to the process of

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82 The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (signed 15 April 1994, entered into force 1 January 1995).

83 This point was emphasised by White J in the Court of Appeal: *New Zealand Pork Industry Board* (CA), above n 64, at [113]. We note that the requirements for meeting New Zealand's international biosecurity obligations are now specified in more detail in s 23 of the Biosecurity Act, especially s 23(4)(b)(iv) and 23(4)(c) (as inserted from 18 September 2012 by s 20 of the Biosecurity Law Reform Act).

giving effect to these objectives is risk assessment. The difficulty with risk assessment in this context was summarised by the review panel in its report as follows:

> Almost all risk analyses are conducted in situations where the scientific evidence is incomplete and a balance must be sought between trying to acquire complete knowledge and making predictions with a reasonable level of confidence.

As we shall see, this approach is reflected in the provisions of the SPS Agreement.

[115] Article 5(7) of the SPS Agreement provides for the introduction of temporary import restrictions:[84]

> In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. *In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.*

It was this article that permitted the Director-General to make the provisional import health standards in 2001.

[116] As can be seen from the italicised words, having imposed a temporary measure, the Director-General was obliged to undertake further work. In that context, art 2(2) provides:

> Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

Accordingly, a protective measure must:

(a) be applied only to the extent necessary to protect human, animal or plant life or health;

(b) be based on scientific principles; and

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[84] Emphasis added.

(c) not be maintained without sufficient scientific evidence.

The need for a genuine scientific basis for protective measures is reinforced by art 2(3), which relevantly provides that "[s]anitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade".

[117] Article 3(1) requires member states to base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, for harmonisation reasons. However, art 3(3) does allow member states to introduce protective measures that result in a higher level of protection than would result from the application of international standards, but only if there is a scientific justification or art 5 is complied with.

[118] The principles summarised at [116] above are also reflected in art 5, as follows:[85]

> 1. Members shall ensure that their sanitary or phytosaniatry measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by relevant international organisations.
>
> …
>
> 4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.
>
> …
>
> 6. Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.

In a decision concerning import restrictions imposed by the European Community on beef from animals fed with certain hormones, the Appellate Body of the World Trade Organisation held that art 2(2) is an important part of the context against which art

[85] Footnote omitted.

5(1) must be interpreted.[86] Read against the background of art 2(2), art 5(1) "requires that the results of the risk assessment must sufficiently warrant – that is to say, reasonably support – the SPS measure at stake".[87] The words "based on" in art 5(1) indicate that there must be "a rational relationship between the measure and the risk assessment".[88]

[119] Finally, we mention that there is a dispute resolution procedure under the SPS Agreement,[89] to which New Zealand had resort in its dispute with Australia about the prohibitions on the export to Australia of New Zealand apples.[90] Reciprocity is an important feature of the international arrangements.

Section 22A

[120] Returning to the Act, s 22A provides for an independent review of the Ministry's use of scientific evidence in developing an import health standard. As the review panel noted in its report, a review is limited to the scientific aspects of the case and does not extend to the non-scientific aspects relevant to the chief technical officer's recommendation and therefore to the Director-General's decision. Section 22A relevantly provides:

> **22A Process for independent review panel to be established**
>
> (1) The Director-General must, by notice in the *Gazette*, set out the process by which an independent review panel is to be established to review whether, in developing an import health standard, there has been sufficient regard to the scientific evidence about which a person consulted under section 22(6) has raised a significant concern.
>
> (2) The notice required by subsection (1) must cover the following matters:
>
> (a) the criteria for setting up an independent review panel; and

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86 *EC Measures Concerning Meat and Meat Products (Hormones)* WT/DS26/AB/R and WT/DS48/AB/R, 16 January 1998 (Report of the Appellate Body) [*EC – Beef Hormones*].

87 At [193].

88 At [193].

89 World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures, art 11.

90 World Trade Organisation "Australia – Measures Affecting the Importation of Apples from New Zealand" <www.wto.org>.

(b) how the Director-General will appoint an independent review panel, including the knowledge and experience required for appointees; and

(c) the procedures to be followed by—

(i) a person eligible to seek a review under subsection (1); and

(ii) an independent review panel, in undertaking its review; and

(d) the reporting requirements for an independent review panel.

(3) The Director-General must receive any report from an independent review panel and, as soon as is reasonably practicable, determine the issue in dispute after taking into account the findings and recommendations of the independent review panel, giving reasons for that determination.

…

The Director-General issued the required *Gazette* notice on 26 June 2008.[91]

[121] Section 22A was enacted in 2008[92] in response to the decision of the Court of Appeal in *National Beekeepers' Association of New Zealand v Chief Executive of the Ministry of Agriculture and Forestry*.[93] That case involved a situation broadly similar to the present. The Court of Appeal held that there were two statutory processes to be complied with there, one under s 22 of the Act and the other under the Hazardous Substances and New Organisms Act 1996. The effect of the 2008 amendments was to replace the process under the latter Act with the s 22A process in contexts such as the present.

[122] The Select Committee dealing with the 2008 amendments reported back to the House in these terms:[94]

> We agree with submitters that the process for assessing the evidence should be transparent and trustworthy. We note that most import health standards are developed in cooperation and collaboration with the appropriate sector.

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91 The Biosecurity (Process for Establishing Independent Review Panel) Notice 2008, above n 79.

92 Section 22A was inserted, as from 9 April 2008, by s 6 of the Biosecurity Amendment Act (No 2) 2008.

93 *National Beekeepers' Association of New Zealand v Chief Executive of the Ministry of Agriculture and Forestry* [2007] NZCA 556.

94 Biosecurity and Hazardous Substances and New Organisms Legislation Amendment Bill 2008 (198-2) (select committee report) at 2.

> We recommend the insertion of new clause 5A [s 22A], requiring [the Ministry] to develop a process for an independent panel to review whether [the Ministry] has had adequate regard to the scientific evidence in cases where significant concerns have arisen during the consultation process on a draft import health standards. The Director-General must, by notice in the *Gazette*, set out a process by which an independent review panel is to be established. We believe that section 22(6) of the [Biosecurity] Act adequately sets out those entitled to seek this review process.
>
> The amendment will provide for the review process to be in place by 1 July 2008. The Director-General will be required to respond formally to the recommendations of the review panel and to have regard to those recommendations when making the final decision on the import health standards.
>
> We believe that the establishment of an independent review panel should allay submitters' concerns.

Issues on appeal

[123] We will address the arguments raised on the appeal in the context of two questions:

(a) Did the Director-General respond lawfully to the report of the review panel established under s 22A of the Act?

(b) Given that the Minister had regard to the EpiX model in making his decision to promulgate the import health standards, were the statutory consultation requirements met?

In addressing these questions, we will outline the arguments and, to the extent necessary, the reasoning of the Courts below.

[124] Before doing so, however, we should mention that Dr Palmer, for the intervener, the National Beekeepers' Association of New Zealand Inc, presented submissions which addressed the application of the precautionary principle to the development of import health standards, a matter emphasised by White J in his dissent in the Court of Appeal.[95] Dr Palmer argued that the precautionary principle requires that preventative action be taken to avoid a risk to biosecurity in conditions of scientific uncertainty. He submitted that the Ministry's "application of biosecurity

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[95] *New Zealand Pork Industry Board* (CA), above n 64, at [114].

law … is too biased towards assuming free trade should occur and insufficiently open minded as to the importance of robust independent scientific analysis". He argued that "the purpose of the Act requires that [the Ministry] may only relax the preventive biosecurity measure of an [import health standard] on the basis of robust independent scientific analysis, which the affected industry has the opportunity to test, and on the basis of a precautionary approach to the biosecurity risks of relaxation".

[125] We consider that it is unnecessary that we address Dr Palmer's submissions on this point in any detail. As he acknowledged, in the *EC – Beef Hormones* case the Appellate Body of the World Trade Organisation addressed the precautionary principle in the context of the SPS Agreement. It questioned the European Community's argument that the precautionary principle had become a principle of customary international law, although it did not express a final view on the point.[96] Nor did it accept that the principle overrode the particular requirements of the SPS Agreement.[97] However, the Appellate Body did accept that the precautionary principle was reflected in the SPS Agreement – in art 5(7) in particular, but also in the sixth paragraph of the preamble[98] and in art 3(3). It will be recalled that art 5(7) allows for the introduction of temporary measures in cases where scientific evidence is insufficient, but then requires the undertaking of further scientific work so that a more permanent decision can be made. Both the sixth paragraph of the preamble and art 3 acknowledge that a member may introduce protective measures which result in higher levels of protection than would be the case if international standards were applied, but these measures must still have a scientific justification or meet the requirements of art 5. We do not see the precautionary principle as being relevant beyond these parameters in the present case.

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96 *EC – Beef Hormones*, above n 86, at [123].

97 At [124].

98 That paragraph provides: "*Desiring* to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by international organisations … , without requiring Members to change their appropriate level of protection of human, animal or plant life or health" (italics in the original).

Was the Director-General's response to the review panel's report lawful?

[126] Naturally enough, Mr Cooke QC for the appellant focussed on the language of s 22A in arguing that the Director-General had acted unlawfully in his response to the review panel's report, the relevant response being that dated 10 April 2011. He noted that under s 22A(1), the objective of a review panel is "to review whether, in developing an import health standard, there has been sufficient regard to the scientific evidence about which a person consulted … has raised a significant concern". In terms of s 22A(3), having received the report, the Director-General must "determine the issue in dispute after taking into account the findings and recommendations of the review panel, giving reasons for that determination" and must do so "as soon as is reasonably practicable". The essence of Mr Cooke's argument was that the Director-General did not do what s 22A(3) directed him to do. Accordingly, he acted unlawfully.

[127] Mr Cooke noted that the Director-General had initially responded to the review panel's report by calling, in his decision issued on 1 September 2010, for more work to be done. This resulted in a report from the expert working group and the EpiX model, on the basis of which the Director-General ultimately made his decision of 10 April 2011. Mr Cooke submitted that the Director-General's determination of 10 April 2011 was inconsistent with the text and purpose of s 22A in the following ways:

(a) It asked the wrong question. The Director-General was required by s 22A(1) to address whether, in developing the import health standard, there had been sufficient regard to the scientific evidence. In fact, however, the Director-General's determination was made on the basis of material that was developed after the review panel had reported (specifically, the EpiX model).

(b) The determination did not address the specific findings of the review panel or give reasons for the determination, as required by s 22A(3).

(c) The determination did not address two significant matters raised by NZ Pork in its submissions, which were referred to the review panel in the Director-General's terms of reference.

(d) The determination was not made "as soon as reasonably practicable" as required by s 22A(3), as the further work which the Director-General required to be completed, and which ultimately formed the basis of his decision, took a year.

We address each issue in turn.

Wrong question asked?

[128] As noted, the Director-General responded to the review panel's report in two documents, both expressed as being decisions under s 22A(3) – one issued on 1 September 2010 in which he called for further work and another issued on 10 April 2011 in which he determined that the import health standards did pay sufficient regard to the science (in part on the basis of the further work carried out since his earlier decision). Of these two documents, it is the latter that NZ Pork's submissions focussed on.

[129] Delivering the decision of the majority of the Court of Appeal, Harrison J noted that the 1 September 2010 decision was expressed to be a determination under s 22A(3) and appeared to determine the issue in dispute.[99] He said:

> [42] In essence, acting on the [chief technical officer's] advice, the Director-General determined that the Panel had correctly concluded that the Ministry had not taken sufficient regard of the scientific evidence in some respects when addressing the draft [import health standards]. In substance, if not in form, this was an acceptance that some of the questions raised by [NZ Pork] before the Panel were justified. In Mr Cooke's terms, they were findings made in [NZ Pork's] favour on disputed issues.

However, the Court went on to determine the arguments on the basis that they had been presented by counsel, the focus being on the 10 April 2011 decision. We will

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99 *New Zealand Pork Industry Board* (CA), above n 64, at [41] per Harrison and Stevens JJ.

adopt that approach also, but only up to a point. As we discuss below, it is artificial to treat the two decisions as independent, stand-alone decisions.

(i) Some further background

[130] Before we address NZ Pork's submissions, we will describe the review panel process in a little more detail. In the terms of reference which he set for the review panel, the Director-General described the purpose of the review as follows:

> 15 The Panel is appointed to consider whether [the Ministry], in developing the provisional import health standards, had sufficient regard to the scientific evidence about which [NZ Pork] has raised a significant concern. The Panel should assess whether [the Ministry's] treatment of the issues, given all the evidence, was reasonably open to it, and whether there is a reasonable chain of logic linking the science to the provisional health import standards.

[131] The Director-General then asked the review panel to consider whether the Ministry had had sufficient regard to the scientific evidence in the following areas:

> (a) The identification and analysis of potential hazards associated with the importation of pig meat and pig meat products.
>
> (b) The likelihood that meat from slaughter weight pigs will contain infectious PRRS virus.
>
> (c) The impact of changes to volumes of trade in pig meat as a result of the proposed changes in the [import health standards].
>
> (d) The impact of changes to the volume and distribution of the waste stream as a result of the proposed changes in the [import health standards].
>
> (e) The likelihood that PRRS-infected imported pig meat will be fed to New Zealand pigs and cause infection.
>
> (f) The structure and inter-relatedness of the New Zealand commercial and non-commercial pig industries, and subsequent exposure and spread risks.
>
> (g) The importance and likelihood of aerosol and "area" spread of PRRS virus between herds.
>
> (h) Quantitative modelling of the risk of PRRS virus exposure and consequence, using the model developed during the [import risk assessment/import health standards] process.
>
> (i) Each of the above issues sits within the context of the overall assessment of risk. The Panel should consider whether [the

> Ministry's] overall treatment of the issues was reasonably open on all the evidence.

[132] Williams J described the review panel's report as "wide ranging and discursive, posing more questions than it answers",[100] a description with which the Court of Appeal agreed,[101] as do we. In its discussion of the issues just noted, the review panel was at some points supportive and at others critical of the Ministry's approach. We can illustrate this by reference to the review panel's discussion of issue (b), the likelihood of meat containing infectious PRRS virus.

[133] The review panel noted that NZ Pork's concern centred on how long the infectious PRRS virus persists in a pig. The review panel observed that the Ministry had originally considered utilising a modelling approach, based on the results of field-based and experimental studies, but had later abandoned that in favour of the more direct estimation method provided by observational studies. The review panel considered that this was the correct approach. It favoured direct estimation because it avoided the greater uncertainty associated with modelling, which, the panel said, "uses a large number of assumptions". The review panel then went on to examine the material that the Ministry had relied upon. It noted that new research concerning diagnostic tests had become available since the Ministry's 2006 risk assessment was completed and commended this to the Ministry. It then discussed the concept of an "infectious dose" and the effects on the survival of the PRRS virus of various storage and handling arrangements for uncooked meat, such as freezing and thawing. The review panel raised several issues about the Ministry's analysis in this area and recommended further work. Finally, the review panel commented on the key observational study that the Ministry had relied on in its 2006 risk assessment. While supportive of the study's approach, the review panel identified some weaknesses in it and, for that reason, made the following recommendation:

> The Panel recommends that [the Ministry] includes the uncertainty related to the likelihood that meat from slaughter weight pigs will contain infectious PRRS [virus] in its [import risk analysis] and establishes the sensitivity of the outcome of the risk assessment to this input value. The uncertainty may be further increased due to the fact that only one study was conducted and the population sampled may be different from populations in other regions or countries.

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100 *New Zealand Pork Industry Board* (HC), above n 68, at [117].

101 *New Zealand Pork Industry Board* (CA), above n 64, at [65] per Harrison and Stevens JJ.

[134] The review panel made a variety of recommendations in its report. Some had relevance primarily to this case, such as those just mentioned. Others, however, were more general in nature. For example, the review panel recommended that the Ministry should make its process of hazard identification explicit, specify the events that would trigger action and generally improve its communication in this respect.

[135] In addition, as we noted earlier, the review panel was conscious that, by the time of its review, the process for the promulgation of the import health standards had been under way for some years and there had been developments in both the science and the availability of data over that period. The review panel thought that further work should be undertaken to ensure that any revised import risk assessment reflected these developments. This was particularly relevant to the question whether the risk assessment should utilise a qualitative or quantitative analytical method.

[136] We pause here to explain the difference between the two methodologies. In its report, the review panel referred to the then current edition of the *Handbook on Import Analysis for Animals and Animal Products* published by the World Organisation for Animal Health (*Handbook*), which contained the following discussion:[102]

> No single method of import risk analysis has proven applicable in all situations, and different methods may be appropriate in different circumstances. A qualitative risk assessment is essentially a reasoned and logical discussion of the relevant commodity factors and epidemiology of a hazard in which the likelihood of its release and exposure and the magnitude of its consequences are expressed using non-numerical terms such as high, medium, low or negligible. … [It] is suitable for the majority of import risk analyses, and is currently the most common type of assessment undertaken to support routine import decision-making. In some circumstances it may be desirable to undertake a quantitative analysis, for example, to gain further insights into a particular problem, to identify critical steps or to compare sanitary measures. Quantification involves developing a mathematical model to link the steps of the risk pathway, which are expressed numerically. The results, which are also expressed numerically, invariably present significant challenges in interpretation and communication.

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[102] Noel Murray and others *Handbook on Import Analysis for Animals and Animal Products* (World Organisation for Animal Health, Paris, 2004) vol 1 at 27. There is now a second edition of the Handbook, the substance of which is not materially different on this aspect: Gideon Brückner and others *Handbook on Import Analysis for Animals and Animal Products* (2nd ed, World Trade Organisation for Animal Health, Paris, 2010) vol 1 at 33.

> Although a quantitative analysis involves numbers, it is not necessarily more objective, nor are the results necessarily more "precise" than a qualitative analysis. Choosing an appropriate model structure, which pathways to include or exclude, the level of aggregation or disaggregation, the actual values used for each input variable and the type of distribution applied to them, all involve a degree of subjectivity. In addition, because data are lacking, some models incorporate expert opinion, which by its very nature is subjective.
>
> Since both qualitative and quantitative analyses are inevitably subjective, how can the degree of objectivity be demonstrated? The solution lies, not in the method chosen, but in ensuring that the analysis is transparent. All the information, data, assumptions, uncertainties, methods and results must be comprehensively documented and the discussion and conclusions supported by a reasoned and logical discussion. The analysis should be fully referenced and subjected to peer review.

[137] The review panel accepted that both methodologies had advantages and disadvantages and said that the choice of which to use was a "key decision" for a risk analyst. In particular, the review panel emphasised that it would be a matter of judgment for the organisation or person conducting the risk analysis to decide whether a qualitative, quantitative or combined approach should be used in a particular case. The appropriate methodology would depend on the particular risk analysis required and the availability of time, data and expertise.

[138] The review panel noted that the Ministry's 2006 risk assessment was largely qualitative, whereas the Neumann/Morris model was a quantitative analysis. The review panel agreed with the Ministry's view that the Neumann/Morris model had significant deficiencies, particularly in relation to the assumptions which it incorporated, so that it required updating. However, the review panel considered that the Ministry and NZ Pork had become "unduly polarised" in their views about which type of modelling should be used and considered that risk managers should base their decisions "on all the available evidence, including quantitative models, if available and of sufficient quality". Therefore, it recommended that the Ministry should look to develop more robust quantitative modelling, with expert input, and then consider integrating the results of this modelling into a revised import risk assessment.

[139] The Director-General's immediate response to this report was formally set out in the decision which he announced on 1 September 2010. As we have said, he

accepted the review panel's recommendations for further work. In particular, he directed the Ministry to develop a quantitative risk analysis based on the Neumann/Morris model, which was to be peer reviewed by an independent expert and then examined by an expert working group comprised of persons nominated by stakeholders. This work was duly undertaken and culminated in the EpiX risk analysis, which the Ministry considered supported its 2006 qualitative risk analysis. The Director-General's decision of 10 April 2011 followed and was substantially based on the work which followed the review panel's report.

(ii) Our evaluation

[140] Mr Cooke argued that the Director-General asked the wrong question because he did not address the issues in dispute, namely the nine issues set out in the review panel's terms of reference. What he was obliged to answer under s 22A(3) was whether, in relation to each of the nine issues, the Ministry's 2006 risk assessment (which was the basis for the provisional import health standards issued in April 2009) had had sufficient regard to the scientific evidence about which NZ Pork had raised a significant concern. Mr Cooke submitted that what the Director-General had actually done in his 10 April 2011 decision was determine that the EpiX model, which had not been consulted upon or subjected to the review panel process, provided an appropriate basis on which to issue the import health standards.

[141] In support of this, Mr Cooke argued that the s 22A process is a dispute resolution process "albeit of a particular kind". The Director-General's role is to "adjudicate" a difference of view between the Ministry on the one hand and the consultee on the other. He submitted that this is apparent from the language of s 22A and from its purpose. As to its language, Mr Cooke emphasised that "the issue in dispute" is considered by an "independent review panel" which makes "findings and recommendations" about which the Director-General must make a "determination" supported by "reasons". All this, Mr Cooke submitted, was the language of dispute resolution. As to purpose, Mr Cooke relied particularly on the passage from the report of the select committee quoted at [122] above. Mr Cooke did note, however, that it was not critical to his argument that the s 22A process be characterised as one of dispute resolution – the critical point was that the mandated process had to be

followed, and it had not been in this case as a result of the work carried out after the review panel's report, which the Director-General took into account in his 10 April 2011 decision.

[142] The relationship between ss 22 and 22A is not set out in the Act with any great specificity. Nor is the relationship between s 22A(1) and s 22A(3). Section 22A(3) requires the Director-General to "determine the issue in dispute". The Court of Appeal held that these words referred back to s 22A(1) – that is, to whether there had been sufficient regard to the scientific evidence in the development of the import health standard.[103] Although Mr Cooke was inclined to argue that the words referred to the nine issues identified in the terms of reference,[104] that was not critical to his position. He argued that, even if the words had the meaning the Court of Appeal ascribed to them, the Director-General was still obliged to determine the specific issues, and to set out his reasons.

[143] Section 22A(1) is backward-looking, in the sense that it asks whether in developing an import health standard there was sufficient regard to scientific evidence about which concern had been expressed. Section 22A(3) is forward-looking, in the sense that the Director-General is required when determining "the issue in dispute" to take into account the findings *and recommendations* of the review panel. This suggests that the Director-General's role is not adjudicative in the sense that Mr Cooke advocated. It is fair to assume that where a review panel makes recommendations, they will generally involve further work. If the Director-General accepts the recommendations and calls for further work, there seems little sense in a requirement that he or she determine the disputed matters (a) before that work is completed and (b) without taking it into account. As we see it, the s 22A process is not concerned with point scoring but with improved decision-making.

[144] This can be illustrated by reference to the review panel's report in the present case. As we have said, the review panel considered that the parties had become "unduly polarised" in their views concerning appropriate modelling approaches – qualitative or quantitative. It did not prefer the approach of one party over the other

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103 *New Zealand Pork Industry Board* (CA), above n 64, at [53] per Harrison and Stevens JJ.

104 By virtue of s 33 of the Interpretation Act 1999, the singular, "issue", includes the plural, "issues".

(which was consistent with what was said in the *Handbook* about the two approaches)[105] but rather recommended an approach that combined qualitative and quantitative assessments. Whether a quantitative approach would affect the outcome of the Ministry's qualitative analysis was, of course, unknown. We consider that it is clear from its report that the review panel was not focussed on determining disputed issues but rather on suggesting ways by which the quality of the final decision could be enhanced, such as by the collection of further data, by taking account of recently available scientific material and by carrying out quantitative modelling. We do not consider that the review panel's approach is inconsistent with s 22A, yet that seems to be the logical consequence of accepting Mr Cooke's submissions concerning s 22A.

[145] Moreover, the characterisation of the Director-General's role in the independent review process as one of dispute resolution does not sit happily with the broader statutory context. Under pt 3, the Director-General performs a regulatory function, in the sense that he or she has the ultimate responsibility for making the decision to issue an import health standard. The Director-General's decision must take account of New Zealand's international obligations under the SPS Agreement, which require a sound scientific basis for trade restrictions. In making the decision, the Director-General is assisted by the Ministry. The Ministry is not a protagonist with sectional interests to pursue – it simply assists the Director-General to make his or her decision within the statutory framework. By contrast, those consulted are likely to represent sectional interests – in this case, groups such as overseas pork producers, pork importers and domestic pork producers.

[146] The Director-General's role under s 22A must be viewed against this background. He or she must reach a view about the scientific concerns raised by the consultee, and must explain that view. But the objective of the s 22A process is not to determine a dispute between the Ministry and the consultee; rather, it is to provide some assurance to the consultee, and more widely, that its scientific concerns have been subject to an independent assessment and to consideration by the Director-General in the light of that assessment. In this way, the s 22A process improves the quality and transparency of the final decision concerning an import health standard.

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[105] See [136] above.

As Ms Gwyn aptly described it, the s 22A process is a review process with a remedial purpose. In the present case, in his response issued on 1 September 2010, the Director-General determined that he would accept the recommendations made by the review panel for further work. Once that work was completed, the Director-General considered that he was in a position to make a final determination under s 22, and he did so in his decision of 11 April 2011. He also responded under s 22A(3) in relation to the matters referred to the review panel.

[147] Like the Court of Appeal, we consider that Mr Cooke's argument that the Director-General had to address the review panel's findings and recommendations on the basis of the material as it stood at the time of the report involves an unduly formalistic approach to s 22A. The Court of Appeal saw the review panel process as a step in the overall process of developing and issuing an import health standard, albeit a very important step.[106] We agree. Obviously, the Director-General's response to a review panel's report will depend upon the nature of the report. It will be obvious from what we have already said that the review panel's report did not lend itself to the Director-General making a formal determination or determinations of the type advocated by Mr Cooke: the report raised rather than answered questions; it made recommendations for further work, in some instances simply because matters had evolved since the Ministry's 2006 qualitative risk assessment; and whether the further work would support or undermine the Ministry's 2006 risk assessment was unknown. We do not see how the Director-General could sensibly have determined the specific issues without knowing the results of that further work. Where new information is becoming available and scientific understanding is evolving, there seems little merit, and much artificiality, in requiring that a snapshot be taken at a particular point in time. Yet that is how Mr Cooke argues s 22A is to be interpreted.

[148] Following on from the decision announced on 1 September 2010, the 10 April 2011 decision paper identified each of the review panel's terms of reference, noted the review panel's recommendations on them, recorded the Ministry's response (which included discussion of the subsequent work), and provided a

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[106] *New Zealand Pork Industry Board* (CA), above n 64, at [59] per Harrison and Stevens JJ.

decision on the point together with a "rationale" explaining the basis of the decision. We consider that this was consistent with the requirements of s 22A.

Panel's findings not addressed?

[149] The essence of Mr Cooke's complaint was that the decision paper of 10 April 2011 did not anywhere address the review panel's findings that were critical of the Ministry's consideration and application of the scientific evidence. The paper did not either accept or reject the review panel's findings, giving appropriate reasons. Mr Cooke argued that the Director-General should have articulated the review panel's findings and then accepted or rejected them, so that there would be "transparency as to the science that underpin[ned] the [import health standards]".

[150] Williams J rejected this argument, on the basis that the evidence showed that, when the Director-General made his decision, he had before him not simply the decision paper but 900 pages of background material, including the review panel's report, all of which, according to his affidavit evidence, he read before making his decision.[107] Accordingly, the Judge was satisfied that the Director-General did take account of the review panel's negative findings.[108] The Court of Appeal also rejected Mr Cooke's contention. The Court considered that the Director-General was obliged to receive and consider the review panel's report and recommendations and to determine the issue in dispute (that is, whether there had been sufficient regard to the scientific evidence), with reasons. But he was not required to address all or any of the review panel's specific criticisms.[109]

[151] It seems to us artificial in this context to focus on the 10 April 2011 decision in the way that Mr Cooke has. Taken together, the Director-General's decisions of 1 September 2010 and 10 April 2011 do specifically address the various matters which the review panel raised and explain how and why the Director-General reached the conclusions that he did. The scientific concerns raised by NZ Pork were dealt with in a reasoned and transparent way, which is what s 22A requires.

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107 *New Zealand Pork Industry Board* (HC), above n 68, at [149].
108 At [151].
109 *New Zealand Pork Industry Board* (CA), above n 64, at [71] per Harrison and Stevens JJ.

Determination not as soon as practicable?

[152] Mr Cooke submitted that the Director-General did not make his determination under s 22A "as soon as reasonably practicable" as his 10 April 2011 decision was made a year after he received the review panel's report. He argued that the one year delay resulted from the misapplication of s 22A. What the provision envisaged, he submitted, was the period of time practically required for the determination of the issues in dispute without any accommodation for further work such as occurred in this case.

[153] Williams J considered that no specific time frame was given in s 22A(3) in recognition of the fact that, depending on the nature of the review panel's report, the time taken by the Director-General to respond would vary.[110] The Court of Appeal considered that Mr Cooke's submissions on this point required acceptance of his principal argument that the s 22A process was a dispute resolution process, which the Court had rejected. The Court considered that the phrase "as soon as reasonably practicable" was "primarily a fact orientated obligation".[111] The Court noted that nothing had been suggested to indicate that the Director-General had unnecessarily commissioned further work or wasted time.[112] The Court concluded that the Director-General had met his timing obligation.[113]

[154] We agree with the conclusions reached by the Courts below. Like the Court of Appeal, we consider that acceptance of Mr Cooke's argument on this point requires acceptance of his argument that s 22A establishes a dispute resolution process of the type he advocated. For our part, we consider that the phrase "as soon as reasonably practicable" was deliberately chosen to reflect the fact that the amount of time that the Director-General will need to respond to a review panel's report will depend on its nature and, in particular, whether it contains recommendations for further work. In the present case, there has been no suggestion that unnecessary work was done or that there were lengthy periods of inactivity after the review panel

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110 *New Zealand Pork Industry Board* (HC), above n 68, at [121].
111 *New Zealand Pork Industry Board* (CA), above n 64, at [66] per Harrison and Stevens JJ.
112 At [67] per Harrison and Stevens JJ.
113 At [68] per Harrison and Stevens JJ.

reported. Given the extent of the additional work recommended, we consider that the Director-General's response was given in a timely fashion.

Two issues in dispute not determined?

[155] Mr Cooke submitted that the Director-General's decision under s 22A(3) was unlawful because he had failed to determine two of the issues in dispute, namely whether the Ministry's risk analysis had had sufficient regard to the available scientific evidence relating to:

(a) biosecurity risks other than PRRS potentially involved in allowing raw pork imports; and

(b) the importance and likelihood of aerosol and area spread of PRRS.

[156] The Court of Appeal rejected this argument, on the basis that the issue in dispute was whether sufficient regard had been paid to the scientific evidence in developing the import health standard rather than the particular issues identified in the terms of reference.[114] But Mr Cooke challenged the Court's analysis on the basis that, even if there was one overall issue, there were still nine sub-issues, which needed a response.

[157] In its report, the review panel noted that NZ Pork had raised the issue of incomplete hazard identification and provided a list of potential hazards in addition to PRRS. The review panel commented: "The basis for this list is not clear nor which criteria were used for inclusion or exclusion of hazards". The review panel then said that it had limited its consideration to PRRS, partly because of time constraints and partly because that was the focus of the Ministry's concern. However, the review panel went on to make some general observations about hazard identification. In the course of that, the review panel noted that the Ministry had said that it routinely monitors new and emerging diseases and had described in its submission its formal process for reviewing emerging risks. The review panel expressed a concern, however, that the outcomes of the Ministry's assessments or

[114] *New Zealand Pork Industry Board* (CA), above n 64, at [75] per Harrison and Stevens JJ.

reviews may not have been publicised appropriately and emphasised the need to have a continuous and documented process in place to monitor changes in risk.

[158] The review panel's recommendations on hazard identification were noted in the decision paper released on 1 September 2010. The paper said that the recommendations would be passed on to the Border Implementation Programme for consideration and noted that, because there were over 300 import health standards in effect, considerable resources would be required to implement aspects of those recommendations. The 10 April 2011 decision paper, having set out the relevant term of reference and the review panel's recommendations, records that both recommendations were noted and passed to the Border Change Programme for consideration. The paper then says:

> There are no specific matters requiring a decision in relation to the pork import health standards and this issue.
>
> The Border Change Programme is a multi-faceted initiative within [the Ministry] to improve the mechanisms through which [the Ministry] develops, communicates and verifies requirements for management of biosecurity risk at the border. The programme has established its own consultation processes involving stakeholders, performance measures, and reporting mechanisms.

[159] We were not referred to anything of substance to indicate that the Director-General should have considered some hazard apart from PRRS in determining whether to issue the import health standards. Against that background, the response given in the two decision papers seems to us to meet the statutory requirements.

[160] In respect of aerosol and area spread, the review panel noted that area spread was poorly defined and understood. It said that the potential for aerosol and area spread between herds was not conducive to laboratory-based science but should be examined in an epidemiological manner. The review panel observed that, at the time of the Ministry's 2006 risk analysis, there was little laboratory research or epidemiological evidence available and commented that the Ministry needed to monitor the results of any studies to obtain relevant information. The review panel briefly discussed biosecurity measures that might minimise the spread of PRRS, and recommended that more recent evidence on this be considered. In relation to aerosol

spread, the review panel recommended the collection of more data about the size, location and quantities of pig herds in New Zealand.

[161] The decision paper leading to the Director-General's decision announced on 1 September 2010 contained comments on these recommendations. First, it noted that herd surveys of the type suggested by the review panel could be carried out but would be expensive and would quickly become outdated. Second, the paper said that the Ministry had discussed the issue of new information about area spread with recognised international experts and would take account of recently published information about biosecurity measures as it came to hand.

[162] In the 10 April 2011 decision paper, the review panel's recommendations were set out and the comments from the earlier paper were repeated. Then the decision paper said:

> There are no specific matters requiring a decision in relation to the pork import health standards and this issue. The likelihood of infection of PRRS in New Zealand pigs arising from imports of pork is so low that there is little value in undertaking further studies on onward spread.

The Ministry made a judgment, on a cost/benefit basis, that no further work was required on this issue. That was its recommendation to the Director-General, who agreed with it. In these circumstances, we consider that the Director-General did determine the two issues raised by Mr Cooke and gave reasons for doing so.

Conclusion on Director-General's response

[163] Accordingly, we do not accept that the Director-General's response to the review panel's report was unlawful in that it did not meet the requirements of s 22A.

Were the statutory consultation requirements met?

[164] Mr Cooke argued that there were two relevant failings in relation to consultation. First, there was no consultation on the revised risk analysis set out in the EpiX model. Second, the simultaneous determination of the matters arising from the review panel's report under s 22A and the import health standards under s 22

prevented any further input into the final decisions before they were made. We address both points together.

[165] Before we do so, however, we make three preliminary points. The first is that, as the extract from the *Handbook* noted, both qualitative and quantitative risk assessments are "inevitably subjective".[115] They are predictive analytical tools, and accordingly involve assumptions about which there may be considerable scope for dispute but which ultimately cannot be objectively verified. In its report, the review panel states:

> 52. Under the SPS Agreement a key question for [the Ministry] is whether the scientific evidence is sufficient in quantity and quality to complete a justifiable risk analysis. Almost all risk analyses are conducted in situations where the scientific evidence is incomplete and a balance must be sought between trying to acquire complete knowledge and making predictions with a reasonable level of confidence.
>
> 53. There is rarely a single interpretation of any scientific issue. Differences in interpretation are normal and a vital part of testing how robust is the evidence supporting any particular conclusion. The key issue is to consider the weight of evidence and whether there is a coherent relationship between the evidence and the conclusions drawn from it.
>
> 54. Science can never prove a complete absence of risk, but it is the basis for an assessment of risk and supporting measures to manage risk. Decisions on import health standards must be made on the basis of the best information available at the time. When issuing import health standards, or declining to issue them, the Director-General must be satisfied that there is sufficient information to support the assessment of risk and the measures identified to effectively manage that risk.

The focus of pt 3 of the Act on the *minimisation* of risk rather than its elimination reflects the reality of scientific analysis in this context.[116]

[166] Later, the Chair of the expert working group provided a summary of the group's process and findings. In the course of his report, he made the following observation about the outcome of the group's deliberations:

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[115] See [136] above.
[116] See [111] above.

> The process was reasonably efficient and effective in drawing out expert opinion relevant to the risk question. Some new scientific information on peak viraemia was presented. Expert opinion varied on the interpretation of this information. Polarised views on some other key issues were encountered early on and did not change through the process. The polarisation was particularly evident on some aspects other than the risk model under consideration, such as whether the empirical evidence of history could be interpreted as indicative of low risk, and whether a domestic culture of waste-feeding and poor compliance represents a justification for import restrictions. The discussion returned to these two aspects repeatedly.

The Chair went on to say that the experts had different views about the validity of the risk model under discussion (the Ministry's revision of the Neumann/Morris model).

[167] The second preliminary point concerns the extent of the obligation to consult. To recapitulate, under s 22(6) and (7), consultation:[117]

(a) must be carried out by the chief technical officer before making a recommendation to the Director-General.[118] The obligation is not that of the Director-General;

(b) is with *representatives* of classes of people having an interest in the standards. No individual interested party has a right to be consulted;

(c) is limited to matters of scientific concern[119] rather than covering all matters relevant to the chief technical officer's recommendation under s 22(5); and

(d) may be on a risk analysis or draft import health standard,[120] at the discretion of the chief technical officer.

Accordingly, while the Act does require consultation in normal circumstances, it is a circumscribed requirement.

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117 Fully set out at [110] above.

118 Subject to urgency and the de minimis principle: see [112] above.

119 Section 22A(1).

120 Section 22(7). We say draft import health standard because the consultation must occur before the chief technical officer makes any recommendation to the Director-General on the issue or amendment of the standard.

[168] The final preliminary point concerns the nature of any consultation. The content of a statutory obligation to consult will be affected by context. So, an obligation to consult before a decision-maker has formulated any proposal is different from an obligation to consult arising after the decision-maker has formulated a proposal. In the present case, because s 22(7) provides that the required consultation may be on a risk analysis or a draft import health standard, the statutory obligation arises after the Ministry has undertaken work rather than from the outset. In this context, the obligation to consult will involve obligations to inform, to listen and to consider. The chief technical officer must tell those to be consulted what is proposed, must give them a fair opportunity to express their views and must consider their views with an open mind before making any recommendation to the Director-General. These principles emerge from the decision of the Full Bench of the Court of Appeal in *Wellington International Airport Ltd v Air New Zealand*.[121] That case also makes it clear that "consultation" is not synonymous with "negotiation" and that there is no requirement that the persons consulted agree with the final decision (in this case, the chief technical officer's recommendation).

[169] Section 22A does not specify the point in the process at which an independent review may be requested. There is some suggestion in the language of s 22A that a review by an independent panel can only take place after an import health standard has been issued or at least released in draft – s 22A(1) identifies the purpose of a review as being to consider whether, *in developing an import health standard*, there has been sufficient regard to the scientific evidence. However, we consider that the language is sufficiently broad to permit a person consulted about a risk analysis to request an independent review of it, given that risk analysis is a critical step in the development of an import health standard.

[170] The question is whether the independent review process under s 22A could give rise to a further obligation to consult under s 22(6). Clearly where the review process accepted that sufficient regard had been taken of the scientific evidence, no further obligation to consult would be triggered. But what is the position where a review concludes that there has not been sufficient regard to the scientific evidence

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[121] *Wellington International Airport Ltd v Air New Zealand* [1993] 1 NZLR 671 (CA) at 674–676.

or does not reach any conclusion about that but does recommend further work, to take account of new data, for example?

[171] The majority in the Court of Appeal considered the terms of s 22(6) and (7) to be decisive on this issue.[122] The chief technical officer's obligation to consult arises before he or she makes a recommendation to the Director-General concerning the issuance or amendment of an import health standard. In the present case, the first import risk assessment and provisional import health standards were issued in mid-2001. The Ministry undertook further work and consultation before releasing its further import risk assessment for consultation on 25 July 2006. On 12 November 2007, the Ministry released the draft import health standards for consultation. On 7 April 2009, the Director-General issued his provisional import health standards, after which NZ Pork requested the appointment of a review panel. The Court regarded what followed after the review panel had reported as essentially a continuation of what had preceded it, so that no new obligation to consult arose. There was no recommendation from the chief technical officer about a new import risk assessment or new import health standard to trigger an obligation to consult.[123] Rather, the import health standards approved by the Director-General in April 2011 were materially the same as the provisional standards published in April 2009.

[172] The majority's judgment is not clear on the question whether there is a further obligation to consult where the scientific basis for a chief technical officer's recommendation has changed substantially as a result of work undertaken following a review panel's report, even though the recommendation itself remains the same. We consider that there would be an obligation to consult further in such circumstances. To take an extreme example, assume that a chief technical officer recommends import health standards on the basis of a risk analysis prepared by the Ministry. Following consultation on the risk analysis, the independent review process is invoked. The review panel concludes that the Ministry's risk analysis has been so poorly carried out that the Ministry should discard it and undertake a new risk analysis, on a different basis and with expert assistance. The Ministry does that.

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122 *New Zealand Pork Industry Board* (CA), above n 64, at [87] per Harrison and Stevens JJ.

123 At [90] per Harrison and Stevens JJ, agreeing with Williams J in *New Zealand Pork Industry Board* (HC), above n 68, at [233].

On the basis of the new risk analysis, the chief technical officer makes the same recommendation to the Director-General as that made previously, without further consultation. In these circumstances, the consultation requirements in s 22(6) would not have been met, the new risk analysis being wholly different from that originally consulted upon.

[173] This does not mean, however, that whenever a review panel recommends further work, there must necessarily be further consultation under s 22(6) after that work is completed. Work of a "tidy-up" nature is unlikely to trigger a further obligation to consult, for example, nor is the updating of existing data where the updated data is consistent with existing data and supports the conclusion already expressed. Ultimately, whether the obligation to consult again is triggered will depend upon the nature, extent and impact of the further work, the focus being on whether the work has led to a substantial change in the scientific basis for the chief technical officer's recommendation. The fact that further consultation is required will not necessarily mean that there must be a further independent review if one is requested, given that the Director-General has some discretion in that respect.[124]

[174] In the present case, the Ministry did undertake further consultation following the independent review. It held a workshop with stakeholders to determine how it should proceed in light of the review panel's report. More importantly, it established the expert working group to consider the result of that further work, namely the Ministry's revised model. NZ Pork nominated Dr Neumann to that group, and he presented a reworking of the Ministry's revised model, the Neumann EWG model, at the end of the expert working group process. This in turn led to the EpiX model.

[175] In the Court of Appeal, the majority did not accept that the EpiX model was a new or fresh import risk assessment. Mr Cooke challenged that finding, relying in particular on Professor Morris's affidavit evidence. Professor Morris expressed the opinion that the EpiX model was "a very substantial underestimate of the risk of a PRRS incursion in New Zealand under the new import health standards". He said

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[124] The Biosecurity (Process for Establishing Independent Review Panel) Notice 2008, above n 79, at cl 9.

that the EpiX model contained several very influential parameters, three of which he used to illustrate what he considered to be its weaknesses:

(a) the amount of pork imported (from any source) – Import_P;

(b) the proportion of imported pork sold as consumer-ready cuts – Consumer Ready_P; and

(c) viral persistence after slaughter – Prop_After_Bleeding.

In his dissenting judgment in the Court of Appeal, White J placed particular weight on this material.[125]

[176] Before addressing the three aspects identified by Professor Morris, we repeat two points. First, over the course of the development of the import health standards, four quantitative risk analyses were developed (in addition to the Ministry's 2006 qualitative risk analysis) – the Neumann/Morris model in 2007, the Ministry's revised model in 2010, the Neumann EWG model in 2010 and the EpiX model in 2010. Each of the 2010 models was a development of what preceded it. Second, as far as Drs Zagmutt and Groenendaal were concerned, the EpiX model did not make any fundamental changes to the structure or logic of the Neumann EWG model, so that it was not a new model. Rather, they saw it as correcting some mistakes and unjustified assumptions in the Neumann EWG model.

Import_P

[177] In its revised model, the Ministry noted that in the year to June 2010, imported pork accounted for 43.7 per cent of the total supply of pork to the New Zealand domestic market. The Ministry said that its revised model accepted the 0.42 value used in the Neumann/Morris model and allowed for up to 50 per cent of consumed pork to originate from overseas to accommodate an assumption that the new import health standard would result in increased imports. Import_P was accordingly described in the Ministry's revised model by "Uniform (0.42, 0.5)".

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125 *New Zealand Pork Industry Board* (CA), above n 64, at [102] per White J.

[178] In the Neumann EWG model, Dr Neumann utilised a new figure for the supply of imported pork to the New Zealand market, namely 60 per cent. This was based on usage estimates provided to the expert working group by Mr Glass, a pork processing expert employed by FreshPork New Zealand Ltd. Mr Glass considered that the 60 per cent figure would result from the volume and price competitiveness of imports. Accordingly, in Dr Neumann's reworked model, Import_P was described by "Normal (.6, .05)". It is apparent from its report that these estimates were discussed at some length by the members of the expert working group.

[179] By way of background, among the issues commented on by the review panel was the likely impact of the introduction of the import health standards on the volume of pig meat imported into New Zealand and the volume and distribution of waste material (such as scraps and off-cuts) that would be produced. The review panel recommended that the Ministry consider collecting information on the potential changes in the volume and source of imported pork and associated waste. Mr Glass addressed these matters in the expert working group, providing estimates of the increased volume of imports that would result and the amount of waste material that would be generated. Dr Neumann utilised these estimates in the Neumann EWG model.

[180] Drs Zagmutt and Groendaal commented on the use of "Normal (.6, .05)" for Import_P in the Neumann EWG model as follows:

> [T]he mean of the Normal distribution was based on Mr Glass's personal estimates, and the .05 standard deviation (standard error) was provided by Dr Neumann. No further references or explanation are given for the choice of parameters.

They said that this difference alone provided an explanation for the large differences between the Ministry's revised model and the Neumann EWG model. Although they accepted other estimates provided by Mr Glass in the EpiX model (in particular, in relation to waste), they decided that they would use the existing parameters for Import_P rather than those suggested by Dr Neumann on the basis of Mr Glass's estimates.

[181] Drs Zagmutt and Groenendaal explained that they did not consider that Mr Glass had justified his 60 per cent estimate, whereas they considered that there was a legitimate basis for the figure adopted by the Ministry in its model. It is, of course, not the Court's role to determine which of these two views is correct; and even if it were, it would be difficult to do so given that Import_P involves a prediction of future market behaviour following a change in regulatory settings.

[182] What is important in this context is that the estimates provided by Mr Glass were discussed in the expert working group, and Mr Glass had the opportunity to explain and defend them. Ultimately no consensus was reached. But it is untenable to suggest that NZ Pork's nominee on the expert working group, Dr Neumann, did not know what was proposed in relation to Import_P and did not have a fair opportunity to express his views. Equally, it is untenable to suggest that the views of Mr Glass and Dr Neumann were not considered in the expert working group process. Ultimately, the advice of Drs Zagmutt and Groenendaal was that the Glass estimate of Import_P should be rejected in favour of the lower figure based on the figure in the Neumann/Morris model and the Ministry's revised model. The Director-General ultimately accepted that advice. But the adoption of an Import_P figure based on the figure used in earlier models did not render the EpiX model a new model.

Consumer Ready_P

[183] Consumer Ready_P was described in the Ministry's revised model by "Pert (0.0095,0.02645, 0.0434)" and in the Neumann EWG model by "Normal (0.2, 0.05)". In discussing this difference, Drs Zagmutt and Groenendaal quoted Dr Neumann's explanation as follows:

> [The Ministry] has used a flawed procedure to conclude that less than 3% of the imported product would be utilised as consumer-ready, whereas [Mr] Glass concluded that it would be about 33%. To avoid unnecessary debate about the exact value which would be reached under the proposed import policy, I have used a figure of 20% in the results reported below.

[184] Again, Drs Zagmutt and Groenendaal considered that insufficient support was provided for Dr Neumann's revised Consumer Ready_P parameter. Given the sensitivity of the parameter, Drs Zagmutt and Groenendaal considered that the Ministry's description of the parameter should be used as the Ministry had shown

how it had been derived from existing data. Again, this parameter was discussed within the expert working group, although no consensus appears to have emerged.

Prop_After_Bleeding

[185] In relation to Prop_After_Bleeding, the EpiX model used the same parameters as were used by Dr Neumann in the Neumann EWG model: "Uniform (0.002, 0.009)". Drs Zagmutt and Groenendaal explained that they had some concern about the parameters, but having conducted a sensitivity analysis they concluded that they did not make a biologically significant difference to the model output. They therefore decided to keep the parameters in the Neumann EWG model. NZ Pork can have no valid complaint about this.

Conclusion concerning parameter changes

[186] Like the majority of the Court of Appeal, then, we reject Mr Cooke's submission that the EpiX model was a new import risk analysis which triggered a further obligation to consult. The EpiX model did not involve a substantially different approach from the Neumann EWG model, nor did it introduce substantially new data or other material. Rather, it involved some adjustments to individual parameters in the Neumann EWG model, parameters which were discussed at length in the expert working group, to which NZ Pork had nominated Dr Neumann.

[187] In his dissenting judgment, White J considered, on the basis of Professor Morris's affidavit, that there remained "a genuine and unresolved scientific issue as to the risks involved in the importation of raw pig meat …".[126] It is true to say that there was a difference of opinion among the experts as to some of the parameters to be used in the risk analysis. That is hardly surprising. As we have said, risk assessments, even quantitative ones, inevitably contain subjective elements.[127] To the extent that they involve assumptions and predictions, they involve uncertainty – and with uncertainty comes scope for differences of view. But consultation does not have to lead to consensus. It requires the decision-maker to consider in good faith the views that consultees have expressed about what he or she proposes to do.

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126 *New Zealand Pork Industry Board* (CA), above n 64, at [103] per White J.

127 At [136] above.

[188] The parameters utilised in the EpiX model were discussed in the expert working group and the various arguments about them were aired. At some point in the process, a decision had to be made even though consensus was not forthcoming. In this connection, the observations of Drs Zagmutt and Groenendaal in their discussion of the EpiX model are pertinent:[128]

> A typical situation occurring while performing quantitative risk assessments is that the more the analyst, decision makers, and stakeholders think about the risk and the limitations of the model, the more complexity and/or collection of further data the analysts are encouraged to pursue. *However, at some point further collection of data or improvements to the modelling methods may not provide incremental information to make a biological difference that may affect the decision to be supported with the model.* We have attempted to point out the parameters and data that could be further refined while also considering whether those refinements can make a significant difference in the model predictions.
>
> From this work, it is our belief that the current model provides a conservative estimate of the risk of introduction of [PRRS] into New Zealand via the importation of fresh pork meat …, and therefore any further modelling work or collection of new evidence should only be considered if either the current risk is not acceptable for the decision maker, or if new evidence will show that in fact the model underestimates the risk. In our experience, the former is possible but the latter is less likely given all the time, auditing, and discussions that have revolved around this particular risk assessment model.

[189] The Director-General had all this material before him when he made his decision. He decided to accept the analysis in the EpiX model despite the different parameters used in the Neumann EWG model, which produced a different outcome. As the extract which we quoted from the *Handbook* indicates,[129] a decision-maker can bring some objectivity to an inherently subjective process by ensuring that the analysis is transparent:

> All the information, data, assumptions, uncertainties, methods and results must be comprehensively documented and the discussion and conclusions supported by reasoned and logical discussion. The analysis should be fully referenced and subjected to peer review.

As we see it, this is what the Director-General was intending to achieve in the present case through the processes he implemented over a lengthy period. Against

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[128] Emphasis added.

[129] See [136] above.

this background, we consider that the Director-General was entitled to make a decision at the time he did.

Sensitivity analysis

[190] Finally, we address Mr Cooke's submission that the combined effect of the changes to the parameters mentioned above was that the estimated frequency of PRRS outbreaks was much lower in the EpiX model than in the Neumann EWG model. Given the sensitivity of the parameters, Mr Cooke argued, further consultation on the EpiX model was required.

[191] The members of the expert working group discussed sensitivity issues, as did Drs Zagmutt and Groenendaal. The impact of the changes to particular parameters was well understood. Again, we consider that the Director-General was entitled to make a decision on the basis of the material before him. There was no obligation to consult further on this account.

Conclusion

[192] We summarise our conclusions as follows:

(a) The Director-General responded lawfully to the report of the review panel established under s 22A of the Act.

(b) The consultation obligations contained in s 22(6) of the Act were met.

Result

[193] For these reasons, we dismiss the appeal. The appellant is to pay costs of $25,000 to the first and second respondents collectively, plus reasonable disbursements as fixed by the Registrar.

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