Supplementary Risk Analysis: Extension of countries eligible to export frozen, skinless, boneless fillet meat of *Pangasius* spp. under the import health standard fisfilic.spe

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Executive summary

In response to requests to extend the list of countries from which it is permissible to import frozen, skinless, boneless fillet meat of *Pangasius* spp. a supplementary risk assessment was carried out.

The current import health standard (IHS) permits entry of the commodity only from Vietnam. Malaysia was assessed with a view to making this a specified country for import. No changes were suggested to the commodity definition.

Recent scientific literature on *Pangasius* spp., published since the original risk analysis was completed, was examined, as was the health status of pangasid catfish in Malaysia. One parasitic organism and nine bacterial organisms were identified as potential hazards not covered by the original risk analysis. No additional viral or fungal pathogens were identified. Assessments of the additional organisms determined that none represented a risk in the defined commodity.

It was concluded that Malaysia can be specified as a country from which the commodity may be imported under the terms of the existing IHS, without adversely affecting the current level of risk.

1. Background

The import requirements for skinless, boneless, frozen *Pangasius* spp. fillet meat, encompassed within the Import Health Standard (IHS) fisfilic.spe, was finalised in September 2009. This IHS limited the importation of frozen, skinless, boneless fillet meat of *Pangasius* spp. to that produced in Vietnam.

There have been requests to extend the IHS to include Malaysia, but not to amend the commodity definition and thus it remains the same regardless of country of origin.

The original risk analysis, from which the IHS was developed, was comprehensive in its consideration of the global risks from pangasid catfish; the extension of country of origin requires only a review of pathogen reports since 2007, and any specific reports from Malaysia.

This document details the results of this additional consideration.

2. Review of original risk analysis

The original risk analysis (Johnston 2008) covered a number of pathogens that have been identified in Malaysia. In all cases it was determined that risk management measures were not required.

Myxobolus baskai and *Myxoblous pangasii* are myxosporeans that parasitise the gill capillaries and splenic serosa respectively.

Hemigoides berlaudi, *H. malayensis,* and *H. pangasii* are myxosporeans found on the gills and within the gill arteries and cartilage.

Henneguya shariffi is also a myxosporean found on the gills.

The removal of viscera and gills mean these organisms would not be associated with the commodity. For this reason, *Myxobolus, Hemigoides* and *Henneguya* spp. were considered of negligible risk in the original risk analysis, and will not be considered further in this risk analysis.

Protocladorchis pangasii is a trematode found in the intestines of affected fish. The original risk analysis assessed that removal of the viscera during processing would prevent its entry in the commodity, so *Protocladorchis pangasii* does not require further consideration in this risk analysis.

Thaparocleidus spp. are monogenean parasites, and those identified in pangasid catfish in Malaysia have a predilection for the gills, so would be removed during the production of this commodity. Monogeneans have been shown to be highly host specific (Whittington *et al.* 2000), so would not establish in native fish species. For these reasons, *Thaparocleidus* spp. were assessed as being of negligible risk in the original risk analysis, and will not be considered further in this risk analysis.

Aphanomyces invadans, the causative agent of epizootic ulcerative syndrome (EUS), is not considered by the OIE to infect Pangasidae or Siluriformes, but infection has been recorded in many fresh water fish species. The original risk analysis assessed that if overt disease did occur, skin lesions should be apparent and preclude harvesting of the fish for human consumption. General sanitary measures specified in the risk analysis would cover clinically affected fish. Subclinical infections may occur but fungal hyphae are unlikely to penetrate to the musculature in the absence of obvious skin ulceration. Even if spores or hyphae were present in the fillets, these are likely to be inactivated by freezing to -20^{o}C for 72 hours. For these reasons, the original risk analysis assessed that the likelihood of viable spores in the commodity was negligible, and *Aphanomyces invadans* will not be considered further in this risk analysis.

3. Analysis of relevant literature

Available scientific literature was consulted for any reports of pathogens (viral, bacterial, fungal or parasitic) associated with *Pangasius* spp. to cover the time period from the drafting of the risk analysis to the current time. In addition, information was sought from available sources on fish health considerations from Malaysia.

3.1. REPORTS TO THE NETWORK OF AQUACULTURE CENTRES IN ASIA-PACIFIC:

Malaysia is a member of, and reports to, The Network of Aquaculture Centres in Asia-Pacific. Four pathogens reported from Malaysia were considered.

Streptococcus spp. were reported from Malaysia but the host fish not specified. There are no reports in the literature of Streptococcal disease in pangasid catfish.

These bacteria can produce septicaemic disease in fish, with clinical signs including skin haemorrhage and ulceration, and abnormal behaviour (Austin and Austin 1999). *Streptococcus* spp. were considered in a previous risk analysis (Johnston 2008a). The previous risk analysis considered that diseased fish rapidly show clinical symptoms related to septicaemia and would not be harvested for human consumption. If they were, muscle tissue would contain fewer bacteria than the discarded viscera. Subclinical carrier fish that were harvested would contain bacteria concentrated in the gills, eyes, liver, spleen and kidney, which are all organs removed during processing. For these reasons, the previous risk analysis assessed the risk of susceptible native fish being exposed to exotic pathogenic strains of *Streptococcus* spp. from infected fillet meat in the aquatic environment in sufficient quantities to produce an infective dose as negligible. No further assessment is required in this risk analysis.

Grouper iridoviral disease was reported in Malaysia (host species unknown), but this pathogen has not been reported in pangasid catfish in the literature.

Viral encephalopathy and retinopathy (VER), or viral nervous necrosis (VNN), was also reported from Malaysia. There are no literature reports of the virus in pangasid catfish. This virus has a predilection for the brain and eye and may be found in lower titres in a variety of visceral organs; all would be removed during processing and not present in the commodity.

Red seabream iridoviral disease was suspected but not confirmed in one report from Malaysia. This is a marine fish virus that was considered and ruled out in the original risk analysis.

3.2. REPORTS OF DISEASE IN PANGASID FISH IN MALAYSIA SINCE THE ORIGINAL RISK ANALYSIS

The literature revealed two recent reports of disease in pangasid fish in Malaysia.

A new myxosporean, *Myxobolus omari*, was found in the muscles of *Pangasius hypopthalmus* in Malaysia (Szekely *et al*. 2008). No associated major pathological changes were found.

Myxobolus spp. were considered fully in the original risk analysis, where it was acknowledged that some species parasitise muscle tissue so could be associated with the commodity. However, *Myxobolus* spp. are common in the aquatic environment and have been reported in New Zealand. *Myxobolus* spp. tend to be host specific and require specific oligochaete intermediate hosts making it highly unlikely that this species could establish in fish species here. Furthermore, despite the findings of *Myxobolus* spp. in human stools, there is no evidence that these organisms are pathogenic to humans. Therefore, *Myxobolus* spp. will not be considered further.

Bacteria were isolated from diseased ornamental fish, including *Pangasius sutchi*, from Malaysian pet shops (Najiah *et al*. 2008). Isolates were of the bacteria *Flavobacterium* sp., *Aeromonas hydrophila, Edwardsiella tarda*, *Yersinia* sp., *Stenotrophomonas maltophilia*, *Serratia marcescens*, *Acinetobacter baumannii*, *Acinetobacter lwoffi*, *Enterobacter* sp., and *Chromobacterium violaceum.*

Flavobacterium spp. were considered in the original risk analysis. They are generally ubiquitous freshwater organisms and can cause surface lesions on fish under conditions of stress or poor water quality. The previous risk analysis discussed that *F. columnare* is considered to be present in New Zealand, but there are more virulent genomovars which are considered to be exotic. The primary site of attachment and action on the fish is the gills and skin. The process of heading, gilling, eviscerating and skinning would effectively remove the bacteria from the commodity. In addition, washing the product in potable water would reduce contamination. If a highly virulent genomovar was present, the muscle lesions would result in rejection of the fillets for processing. For these reasons, the original risk analysis concluded the likelihood of the organism entering the aquatic environment in sufficient quantities to produce an infectious dose as negligible. *Flavobacterium* spp. will not be considered further in this risk analysis.

Aeromonas spp. were considered in the original risk analysis. They are generally ubiquitous opportunist bacteria common in New Zealand, including *A. hydrophila*. *A. salmonicida*, both typical and atypical strains, are considered exotic to New Zealand, and neither have been reported from pangasid catfish. The most common clinical sign of infection with atypical *A. salmonicida* is skin ulceration, and it is unlikely that clinically diseased animals will be harvested for export processing. If fish subclinically infected with an atypical *A. salmonicida* subspecies, or showing very early signs of skin lesions, were harvested it is unlikely that the bacterium would be present systemically to any significant degree. Finally, the commodity will be frozen. The original risk analysis cited studies in Canada indicating that *A. salmonicida* undergoes a 100-fold decrease in titre when flesh is frozen to -20°C for 5-7 days. Combined with very low expected muscle titres, the original risk analysis assessed the likelihood of viable atypical strains of *A. salmonicida* being present in the commodity as negligible. *A. salmonicida* will not be considered further in this risk analysis.

Edwardsiella tarda is considered exotic to New Zealand, and has been considered in a previous risk analysis (Johnston 2008b). *E. tarda* may be found in the intestinal tract of a

number of aquatic organisms, including carrier fish, and is ubiquitous in the environment in endemic areas. *E. tarda* has a broad host range including both marine and freshwater fish species present in New Zealand waters. The previous risk analysis covered that disease usually only occurs in stressed or injured fish and is linked to poor water quality. In diseased fish, the bacterium causes a generalised enterohaemorrhagic septicaemia, characterised by haemorrhages on the skin and mouth and cutaneous ulceration, sometimes extending to deeper muscle necrosis. The bacterium will survive for up to 50 days in whole fish frozen to -20 °C. The concentration of the bacterium in muscle tissue is expected to be extremely low unless the fish is demonstrating necrotic muscle lesions, which would preclude the fish from being processed. *E. tarda* is considered zoonotic, though infection is rare and is associated with consumption of raw fish or contamination of wounds. There are no reports of the spread of *E. tarda* from human consumption of fish. The previous risk analysis found that the likelihood the commodity would result in increased exposure and disease in the public is negligible.

Exposure of susceptible native fish would require imported fillets or scraps infected with *E. tarda* entering the aquatic environment in sufficient quantities to produce an infective dose, which is highly unlikely for the reasons already outlined and because the commodity is highly processed. Taking these factors into consideration, the previous risk analysis assessed the risk from *E. tarda* to be negligible, and it will not be considered further.

Yersinia ruckeri has been fully considered in a previous risk analysis (Johnston 2008c). *Y. ruckeri* is the cause of enteric redmouth (ERM) disease in a range of fish species including salmonids. There are a number of strains causing the more serious ERM and the milder yersiniosis. This organism has been isolated from New Zealand. Yersiniosis is a disease of fish stressed by poor water quality, and a carrier status can exist. The bacterium will remain viable in frozen fish for over six months, but it is unlikely that muscle titres would be significant unless the fish were suffering clinical disease rendering the fish unsuitable for processing. The risk therefore arises from carrier fish. These fish carry the bacterium mainly in the posterior intestinal tract but also in the kidneys and spleen, and inconsistently in lymphoid tissue, and processing removes these portions of the fish. Hence, although any *Y. ruckeri* present in fillet meat is likely to survive freezing and transport to New Zealand, the risk of entry is low. There are no reports of the spread of *Y. ruckeri* via fish for human consumption. Exposure of susceptible native fish to *Y. ruckeri* would require imported fillets or scraps derived from them entering the aquatic environment in sufficient quantities to produce an infectious dose. Taking all these factors into consideration, the previous risk analysis assessed the likelihood that *Y. ruckeri* would be exposed to, and establish in, native fish to be negligible, and no further assessment is required.

Stenotrophomonas maltophilia is found in aquatic environments, and is an opportunistic pathogen. The organism has been reported in New Zealand (Landcare Research database 2010). S. *maltophilia* was responsible for an outbreak of disease in channel catfish (*Ictalurus punctatus*) (Geng *et al.* 2007), but the organism has not been reported in pangasid catfish. Also, the bacteria were isolated from the kidney and liver of the diseased channel catfish, so would not be associated with the processed commodity. For these reasons, *S. maltophilia* will not be considered further in this risk analysis.

Serratia marcescens is a ubiquitous opportunistic bacterium in the environment, and has been reported in New Zealand (Landcare Research database 2010). *S. marcescens* has been

identified as potentially highly pathogenic to fish (Baya *et al.* 1992). The organism was isolated from water and catfish intestinal contents in the US (Paola *et al.* 1995). Evisceration would ensure the organism would not be present after processing so would not be present on the commodity. The organism does not pose any greater risk than other opportunistic pathogens, and will not be considered further in this risk analysis.

Acinetobacter spp. are opportunistic pathogens widely distributed in nature, and have been reported in New Zealand (Landcare Research database 2010). In a reported study (Xia Lu *et al.* 2008) one bacterial strain of *Acinetobacter baumannii* was isolated from diseased channel catfish (*Ictalurus punctatus*) in China. Exophthalmia, pale liver, and empty stomach were the main clinical signs in the affected fish, and the liver was thought to be the major target organ. The organism has not been reported in pangasid catfish, and would be removed during processing so would not be present in the commodity. The risk posed by *Acinetobacter* spp. is therefore considered to be negligible.

Enterobacter spp. are ubiquitous opportunistic bacteria and may be associated with water and catfish intestinal contents (Paolo 1995). *Enterobacter* spp. are endemic to New Zealand (Landcare Research database 2010). Evisceration and the use of potable water during processing would mean that the bacteria would not be associated with the commodity. *Enterobacter* spp. do not present a greater risk than any other opportunistic pathogen and do not require further consideration in this risk analysis.

Chromobacterium violaceum is a common soil and water organism (Holt *et al.* 1994). *C. violaceum* is associated with tropical and subtropical environments. Typically, it is considered a bacterium of low virulence although, uncommonly, it causes serious pyogenic or septicaemia infections of mammals, including humans. *C. violaceum* was among the bacteria isolated from giant catfish in Thailand associated with a high bacterial load in the water (Purivirojkul 2005). Erythrodermatitis was diagnosed in carp (Kozinska and Antychowicz 1996), resulting in the isolation of four unknown bacteria, one of which had morphological and biochemical characteristics resembling those of *C. violaceum* with the exception of indole production and utilisation of d-mannitol. Infection would be expected to cause skin disease in immunosuppressed fish so affected fish would not be harvested. *C. violaceum* does not present a greater risk than any other opportunistic pathogen, and does not require further consideration in this risk analysis.

4. Conclusion

Having examined novel scientific literature published since the original risk analysis was drafted, and the reported pathogen burden of catfish in Malaysia, it is concluded that ten additional potential hazards could be associated with the fish from which the commodity is derived.

Further assessment of these organisms resulted in none being considered an actual hazard in the commodity when all aspects of the commodity definition in the original risk analysis are considered.

It is therefore concluded that frozen, skinless, boneless fillet meat of *Pangasius* spp. from Malaysia can be regarded as being equivalent to the product from the country already specified, under the conditions required in the existing IHS (fisfilic.spe).

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♣ abstract only

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