Ministry for Primary Industries
Manatū Ahu Matua

Food safety risk assessment for the use of PIT tags in the SNA 1 tagging programme

New Zealand Fisheries Assessment Report 2018/2

David A. J. Middleton
Oliver L. Wilson
Cathy Webb
Jack Fenaughty

ISSN 1179-5352 (online)
ISBN 978-1-77665-770-4 (online)

January 2018

New Zealand Government

Growing and Protecting New Zealand

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Ministry for Primary Industries
PO Box 2526
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This document provides a food safety risk assessment for the proposed use of passive integrated transponder (PIT) tags in a SNA 1 tagging programme. The Ministry for Primary Industries has proposed carrying out a tagging programme to improve the stock assessment for the SNA 1 stock. The last tagging programme in SNA 1 (which used coded wire tags rather than PIT tags) dates from 1994, and recent trends in biomass have been estimated from catch per unit effort indices.

PIT tags represent a physical contaminant in snapper sold whole. The food safety risks arising from the use of PIT tags are considered in terms of reputational risk to seafood processors and the risk of harm to seafood consumers. The food safety hazard persists after the scanning for tags required to meet stock assessment objectives would, under current programme designs, be concluded.

Several High risks from the use of PIT tags in a SNA 1 mark-recapture programme are apparent:

- In the case of Governance hazards, the risk ratings highlight the need for risk management planning to be put in place by food processors to avoid legislative exposure or reputational harm.
- A High risk rating in the case of commercial processing arises due to fishmeal production. Exposure in this case is not well characterised as the extent to which snapper is used in fishmeal is not documented.
- Information from processors on the frequency with which tags are found in the body wall of processed fish tagged in aquaculture operations indicates that there is a High risk of tags being inadvertently implanted in the gut wall rather than the gut cavity.
- The highest risk rating to seafood consumers arises from the risk of choking, as this is the only likely injury where death is a potential outcome.

Under the tagging designs being considered, not all of the commercial catch would be scanned. Nevertheless, the probability that a consumer will encounter a tag in a fish is very low. For example, encounter rates are expected to be orders of magnitude lower than the USFDA standard for pit fragments in olives or the CODEX standard for bones in fish fillets.

In managing these risks, the detectability of the chosen tag type before and during processing is extremely important.

1. INTRODUCTION

The Ministry for Primary Industries has proposed undertaking a mark-recapture programme for the snapper (*Pagrus auratus*) stock on the north-east coast of the North Island (SNA 1) to provide data that are used to estimate abundance and movement within an integrated stock assessment model.

A variety of similar programmes have previously been carried out for SNA 1 and other New Zealand snapper stocks. The most recent programme was for snapper on the west coast of the North Island (SNA 8) in 2002 and 2003 (Ministry for Primary Industries 2016). That programme made use of passive integrated transponder (PIT) tags to mark fish, and it has been proposed that a new SNA 1 programme would again use PIT tags (McKenzie et al. 2015).

PIT tags are a type of Radio Frequency Identification (RFID) tag. The tags are encapsulated electronic devices that return a unique identification code to a tag reader. They are passive devices that use the radio energy transmitted by the reader rather than containing a power source. Marking snapper using PIT tags would involve injecting the tag into the gut cavity of the fish. The tags are cryptic: it is not possible to visually distinguish a fish that has been tagged. Less invasive tagging methods (e.g., genetic 'tagging', which makes use of genetic techniques to identify individual fish, or the use of natural markings) were discussed by McKenzie et al. (2015) but not considered sufficiently well developed at that time to be used in an operational mark-recapture programme.

Snapper are tagged after being caught by normal fishing methods[1] and are then released alive back into the population. The process of identifying fish containing internally inserted PIT tags makes use of electronic tag readers and is commonly referred to as 'scanning'. The scanning of commercial catches from SNA 1 (and, to a lesser extent, the recreational and customary catches) provides the opportunity to identify recaptures of previously tagged fish.

The northern snapper fishery (SNA 1) is generally considered to be New Zealand's most important inshore finfish fishery. Consequently, the potential introduction of PIT tags into fish that are destined for human consumption raises issues of food safety. PIT tags are frequently encapsulated in glass. During a previous snapper tagging programme, concerns about the introduction of glass into food product led to the development of a plastic-encapsulated PIT tag (McKenzie et al. 2006). While these plastic-encapsulated tags are frequently described as 'food safe' tags (e.g., Hallprint 2017, Harley et al. 2008), this appears to be simply due to the use of a USFDA-approved surgical plastic to encapsulate the tag instead of glass. Consequently Frusher et al. (2009) noted that 'there remain concerns about the ingestion of the tag by consumers'.

An update of New Zealand's Food Act in 2014 motivated the Ministry for Primary Industries to contract a new food safety risk assessment rather than accepting the use of PIT tags on the basis that their historical use in the previous SNA 8 tagging programme was carried out without any known harm to consumers.

The New Zealand Food Safety Risk Management Framework (NZFSA 2010) aims to separate the processes of risk assessment and risk management, to the extent practicable. This report focuses on risk assessment, defined as 'a scientifically based process consisting of hazard identification, hazard characterisation, exposure assessment and risk characterisation'. In the context of a HACCP (Hazard analysis and critical control points) approach, this report constitutes a hazard analysis and will assist in subsequent identification of critical control points.

This document will be reviewed by the New Zealand Seafood Standards Council, then provided to seafood processors involved in the SNA 1 fishery in order that they can address the risks in their risk management frameworks. It is intended to assist in the open exchange of ideas between risk assessors, risk managers and other stakeholders involved in food production from the SNA 1 fishery.

[1] Primarily bottom-longline fishing, although the use of the developing Precision Seafood Harvesting Modular Trawl System might also be considered.

1.1 PIT tag use internationally and in New Zealand fish

Globally, PIT tags have been used extensively in fisheries research (Gibbons & Andrews 2004) although their use in mark-recapture studies designed to estimate stock abundance is relatively uncommon. Other than New Zealand's 2002 SNA 8 tagging programme (Davies et al. 2013), other programmes that focus on the use of internal PIT tags to support estimates of the abundance of commercially fished stocks include:

- the Norwegian programme for the north-east Atlantic mackerel stock (Hjartåker 2017);
- the International Pacific Halibut Commission programme for estimating halibut abundance (Forsberg 2010, Kaimmer et al. 2012);
- the Heard Island and the McDonald Islands toothfish stock (Welsford & Ziegler 2013) where PIT tags inserted under the skin on the back of the head are used as a backup tagging method.

A recent study (Le Port et al. 2017) placed plastic-encapsulated PIT tags in 1053 adult (longer than 230 mm) snapper caught within the Cape Rodney-Okakari Point (Goat Island) Marine Reserve near Leigh, north of Auckland, under a permit issued by the Department of Conservation. This was used to undertake a mark-recapture estimate of snapper abundance within the marine reserve. No scanning for tagged fish caught outside the reserve was reported and analyses appear to have assumed a closed adult population within the reserve.

PIT tags have also been used in studies of New Zealand freshwater fish. This includes studies of species used as food, such as eels and trout (McEwan & Joy 2011, Holmes et al. 2014).

PIT tags are commonly used in finfish aquaculture, although often restricted to the brood stock. Leigh Fisheries have processed farmed kingfish stock from NIWA's Bream Bay aquaculture research facility for sale into the domestic market. Many batches of these are PIT tagged (with plastic-encapsulated tags) and these are processed to a headed and gutted form before scanning to ensure tags are removed. On two occasions, tags have been located inside the lining of the gut wall post-processing (Figure 1; Tom Searle, Leigh Fisheries Ltd, pers. comm.). It is not known if this is due to tag placement errors or tag migration and encapsulation.

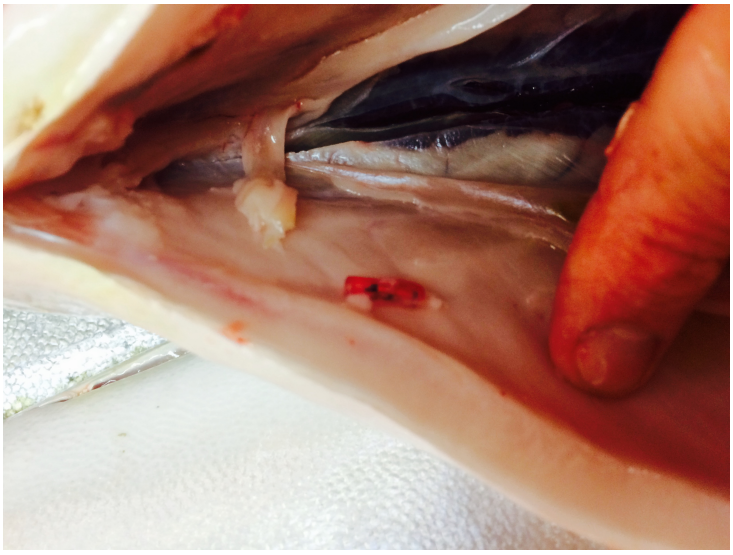

Figure 1: A red, plastic-encapsulated PIT tag located in the gut lining of a kingfish *Seriola lalandi* after processing to a headed and gutted form (photo: Tom Searle, Leigh Fisheries).

Sanford Ltd uses glass PIT tags to identify elite brood stock in their salmon farming operation, tagging around 2000 fish per year. It has been noted that tags are not always successfully implanted into the body cavity and may remain in the flesh of the body wall. Sanford chooses not to market these fish when they are selected for breeding, and destroys the whole fish if the tag cannot be located. While the risk of a tag reaching a consumer is believed to be low, it is considered that the cost of a complaint would be high (Peter Buxton, Sanford Ltd, pers. comm.).

New Zealand King Salmon also uses glass PIT tags in a small number of fish used in trials. These fish are kept separately from untagged stock, and must be gutted and have the tag removed before they enter the processing line. If a tag is not able to be found in a tagged fish then the fish is destroyed (Mark Preece, New Zealand King Salmon, pers. comm.).

2. SCOPE

This risk assessment addresses the food safety hazards arising from the use of PIT tags in the estimation of movement and abundance of snapper in the SNA 1 Quota Management Area (Figure 2).

The scope of this assessment is the impacts of a tagging programme on the production of food for sale, consistent with the Food Act 2014, which 'applies to food for sale'. While it is primarily concerned with commercial fishing for snapper the results of this risk assessment could provide useful guidance to customary and recreational fishers, who currently undertake a significant proportion[2] of the harvesting of snapper in SNA 1, in order that they can mitigate any risks that arise from their harvest of potentially tagged snapper.

This risk assessment does not focus on non-food safety risks associated with a tagging programme, such as health and safety risks to personnel involved in the programme.

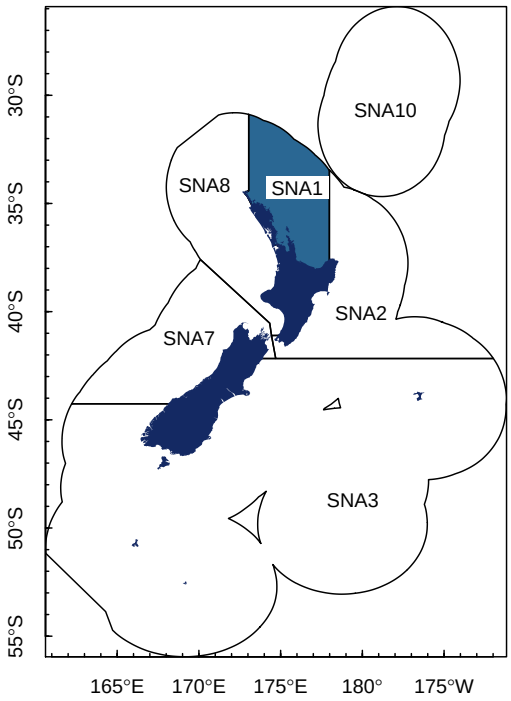

Figure 2: Quota Management Areas (QMAs) for snapper *Pagrus auratus*, with the SNA 1 QMA highlighted.

[2] Approximately 41% based on the current TAC and allowances.

3. METHODS

Following NZFSA (2010, Appendix 1), this risk assessment involves four steps:

1. Identification/categorisation of hazard(s);
2. Evaluation of likely adverse effects associated with hazard(s) [consequence];
3. Characterisation of exposure to hazard(s) [likelihood];
4. Estimation of risk(s).

The estimation of risk is undertaken as a qualitative risk assessment using the likelihood and consequence scales in Appendix A, although some relevant quantitative estimates are available such as the number of tags likely to be contained in unscanned fish (Appendix E).

4. HAZARD IDENTIFICATION

A contaminant in the food safety context is a 'thing which is undesirable, potentially harmful, or unexpected in a particular product or process and is, or may be, present in or in contact with animal material, or animal product or food' (Animal Products Act 1999 s4). In this context PIT tags meet these criteria.

We have grouped the food safety hazards arising from the use of PIT tags into four classes:

1. **Governance hazards** - relating to the legal and administrative food safety hazards associated with the use of PIT tags;
2. **Process hazards** - relating to the food safety hazards associated with the process from inserting a tag into the fish at sea to the processing and selling of product (including the fishmeal process where appropriate);
3. **Physical hazards** - relating to the food safety hazards associated with the physical characteristics of the PIT tag; and
4. **Biological hazards** - relating to the food safety hazards associated with the biological characteristics of PIT tags, such as the release of toxins.

The hazards identified in these different groups are listed in Table 1. We have widened the consideration of hazards to include the potential legal and reputational harm to processing companies as well as addressing the potential for negative health and injury outcomes for seafood consumers.

Not all hazards identified are discrete: for example, implanting malfunctioning tags that will not register on tag readers, or incorrectly placing tags into parts of the fish other than the gut cavity, are contributing factors to the risk that a tag ultimately reaches a consumer's plate. However, in considering the nature of the hazard, and the likelihood of occurrence, it is helpful to consider these issues as different hazards. We have incorporated multiple processing streams in our thinking – for example, commercial processing of snapper may include both filleting of fish, and the production of fishmeal from processing waste.

Table 1: Hazards arising from the use of PIT tags in the SNA 1 tagging programme.

Classification	Hazard	Person(s) exposed	Potential harm
Governance	Evidence of food safety suitability	Processing company	Legal proceedings and reputational damage
	Acceptability of implantation site	Processing company	Legal proceedings and reputational damage
Process	Tag reaches plate and is identified	Processing company	Reputational damage
	Tag reaches plate and is not identified	Consumer	Adverse health affects from tag (see hazards below)
	Tag implantation into muscle rather than gut cavity	Consumer	Increased risk of tag remaining in food
	Implantation of undetectable tags	Consumer	Increased risk of tag remaining in food
	Tag breaks during commercial processing	Consumer	Decreased tag detection, increased potential for harm
	Tag breaks during food preparation	Consumer	Decreased tag detection, increased potential for harm
	Tag reaches consumer via a species other than snapper	Consumer	Decreased tag detection, increased potential for harm
Physical	Choking	Consumer	Injury or death
	Biting tag	Consumer	Dental damage
	Swallowing tag whole	Consumer	Internal injury
	Swallowing broken tag	Consumer	Internal injury
Biological	Toxins released by tag into food	Consumer	Injury or death

4.1 PIT tag types

PIT tags for animal identification are expected to meet ISO 11784 & 11785, which are international standards that regulate the radio frequency identification of animals. The carrier frequency for animal identification is 134.2 kHz. These devices are inherently short range; Fuller et al. (2008) found that the maximum read distance across a range of tags and tag readers used in North American fish tagging programmes averaged 9.5 cm, and ranged from 2.0–31.3 cm.

A range of different PIT tags, potentially suitable for tagging fish, are available (Figure 3). Two characteristics of PIT tags are especially relevant to a food safety risk assessment:

1. **Tag size**, which determines the detectability of tags, either electronically using a tag reader or manually when processing or preparing fish for consumption;
2. **Tag encapsulation material**, which is either biocompatible glass or surgical-grade plastic.

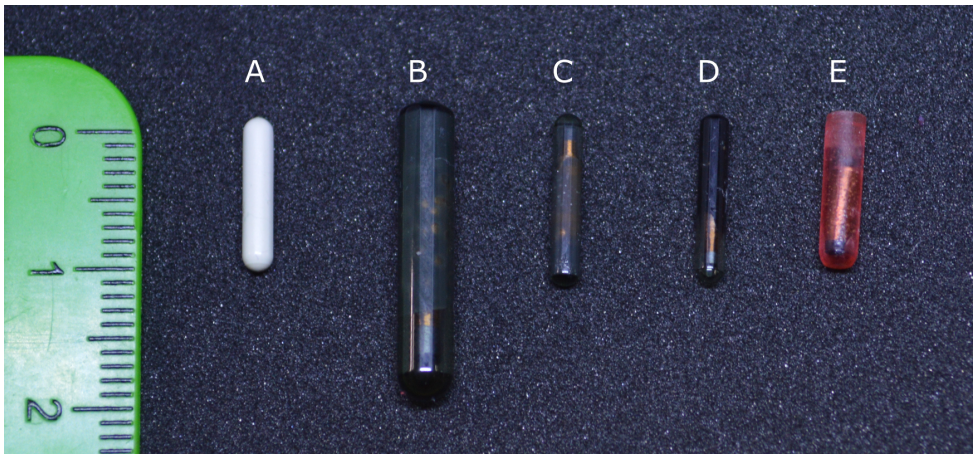

Figure 3: Examples of passive integrated transponder tags designed for tagging fish.

5. HAZARD CHARACTERISATION

The hazards identified are individually characterised below. Each hazard has been assigned a consequence, using the descriptions for reputational damage or injury, as appropriate, contained in Table A-3 of Appendix A.

5.1 Evidence of food safety suitability

5.1.1 Relevant legislation

In New Zealand the key food safety legislation is the Food Act 2014. The purpose of this Act (s4) is to:

(a) restate and reform the law relating to how persons trade in food; and
(b) achieve the safety and suitability of food for sale; and
(c) maintain confidence in New Zealand's food safety regime; and
(d) provide for risk-based measures that—
  (i) minimise and manage risks to public health; and
  (ii) protect and promote public health; and

(e) provide certainty for food businesses in relation to how the requirements of this Act will affect their activities; and

(f) require persons who trade in food to take responsibility for the safety and suitability of that food.

The Act defines 'food' in s9:

(1) In this Act, unless the context otherwise requires, food—

(a) means anything that is used, capable of being used, or represented as being for use, for human consumption ...; and

(b) includes—

...

(v) anything that is or is intended to be mixed with or added to any food or drink; and

...

(c) does not include—

...

(iv) any inedible food-related accessory; or

...

Food is 'unsuitable' under s12(5) of the Act if it:

(c) contains, or has attached to it or enclosed with it, any damaged, deteriorated, perished, or contaminated substance or thing to the extent of affecting its reasonable intended use:

(d) contains a biological or chemical agent, or other substance or thing, that is foreign to the nature of the food and the presence of which would be unexpected and unreasonable in food prepared or packed for sale in accordance with good trade practice.

Seafood, including snapper, is also an 'animal product' as defined by the Animal Products Act 1999 as follows:

animal material means any live or dead animal, or any tissue or other material taken or derived from an animal

animal product, or **product**, means any animal material that has been processed (other than simply transported or stored in such a way as not to involve any alteration to its nature) for the purpose, or ultimate purpose, of consumption or other use by humans or animals.

5.1.2 Legislative risks

Because PIT tags in snapper are a physical contaminant, and foreign to the nature of snapper as a food product, the presence of PIT tags could be considered to render food unsuitable. This represents a risk to seafood processors whose obligation is to ensure that the food they sell 'is safe and suitable' (Food Act 2014 s14). There is an obligation on food processors to consider implementation of risk-based measures that ensure that they achieve safe and suitable food production.

This risk assessment, if judged fit for purpose by the Seafood Standards Council, provides a starting point for food processors to meet their legislative obligations through the implementation of appropriate risk management.

Internationally, the use of PIT tags in fish has been greatest for salmon in North American river systems. In 2015, the PIT tagging programme for the Columbia River system exceeded a cumulative total of 40 million fish tagged (Tenney et al. 2015).

A US manufacturer of PIT tags, Biomark, notes that US government agencies have approved use of PIT tags in fish '... provided that portion of the animal containing the implanted device will not be used for human food' (see Appendix B). As a result, Biomark 'recommend using the body cavity location for all fish that will be released where fish may be caught and consumed' (Biomark 2010).

The majority of New Zealand snapper supplied to export markets are exported whole (Figure 4). As a result the whole fish, including the body cavity where a PIT tag would be implanted, is 'sold as food' for the purpose of the Food Act 2014.

Consequence: Negligible–Moderate, assuming adequate communication of risk management strategy to relevant stakeholders.

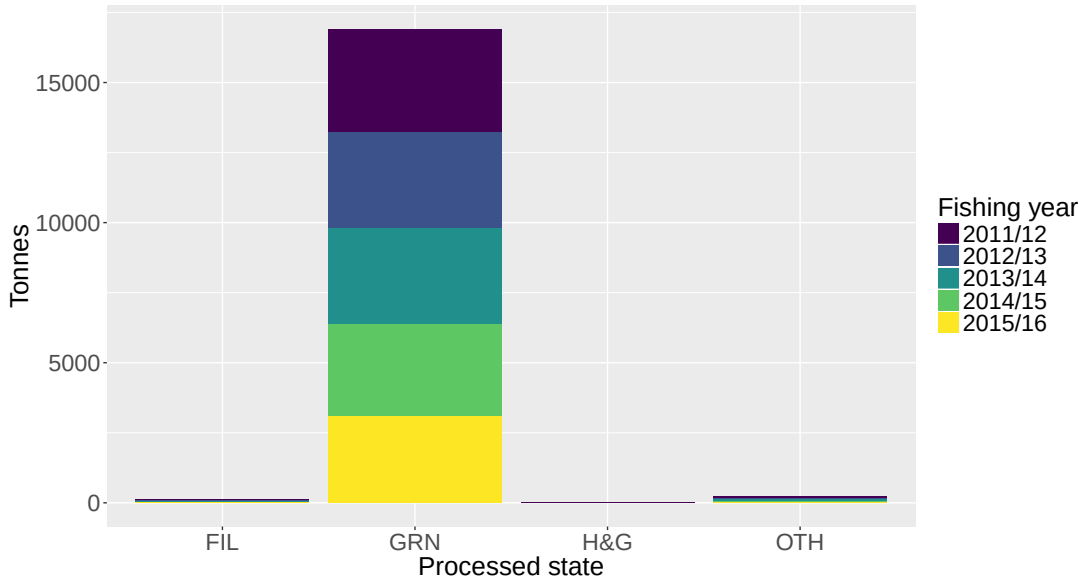

Figure 4: The processed state of snapper exported from New Zealand, by fishing year (Oct–Sept). The form in which the fish are exported has been grouped according to processing state: FIL = fillets, GRN = green (whole), H&G = headed & gutted, OTH = 'other form'. The latter is a specific category used in the export statistics, not a grouping of minor processing states imposed for this analysis.

5.1.3 Export markets

Export statistics from the last five complete fishing years (provided by Seafood New Zealand, using NZ Customs data supplied by Statistics New Zealand) indicate that an average of 3 526 975 kg of snapper were exported annually. This represents 78.4% of the Total Allowable Commercial Catch of SNA 1. The export statistics do not distinguish the originating Quota Management Area, but the SNA 1 TACC represents 70.2% of the total New Zealand-wide TACC for snapper. The average Free on Board (FOB) value of snapper exports over the last five fishing years was $33 840 725.

The majority of snapper are exported to Australia, with the US as the second largest market (Figure 5). Despite claims by a tag manufacturer that 'a number of industry sectors and jurisdictions have recently prohibited the use of glass PIT tags in wild fish studies due to food safety and product liability concerns'[3] no legislation or regulations prohibiting the use of glass PIT tags have been located, and there is evidence of the use of glass tags in both the US and Australia:

[3] SATPOS, Food Safe Tag: 125 & 134.2 kHz plastic tag, http://www.satpos.com/v4/Images/datasheet_foodsafe.pdf.

- as noted above, millions of glass tags have been deployed into salmon and other freshwater fish in the US. In a recent evaluation of PIT tagging procedures for Pacific halibut (Kaimmer et al. 2012), including tag selection, Biomark glass-encapsulated tags were selected; and
- tagging of fish in Australia's Murray-Darling Basin uses either glass or plastic-encapsulated tags.[4]

While European markets for snapper are minor, it is worth noting that the tagging programme for north-east Atlantic (NEA) mackerel[5] has been using glass-encapsulated PIT tags since 2011 (Hjartåker 2017). Scanning of a quarter to a third of the annual NEA mackerel catch has allowed 2500 PIT tags to be recovered, and only a couple have been reported by other companies (not involved in PIT tag scanning) when scanning for metal objects.

A previous NEA mackerel tagging programme, which used steel tags inserted in the abdominal cavity (Tenningen et al. 2011), saw fewer than 10 tags reported by consumers (Aril Slotte, Institute of Marine Research, pers. comm.). Scientists involved in the project request that, if any of the processors receives a customer report of a tag, they should be put in touch with the tagging programme who will forward information about the importance of the process for stock assessment and fisheries management advice. The few consumers who have reported tags have been happy to hear about the project.

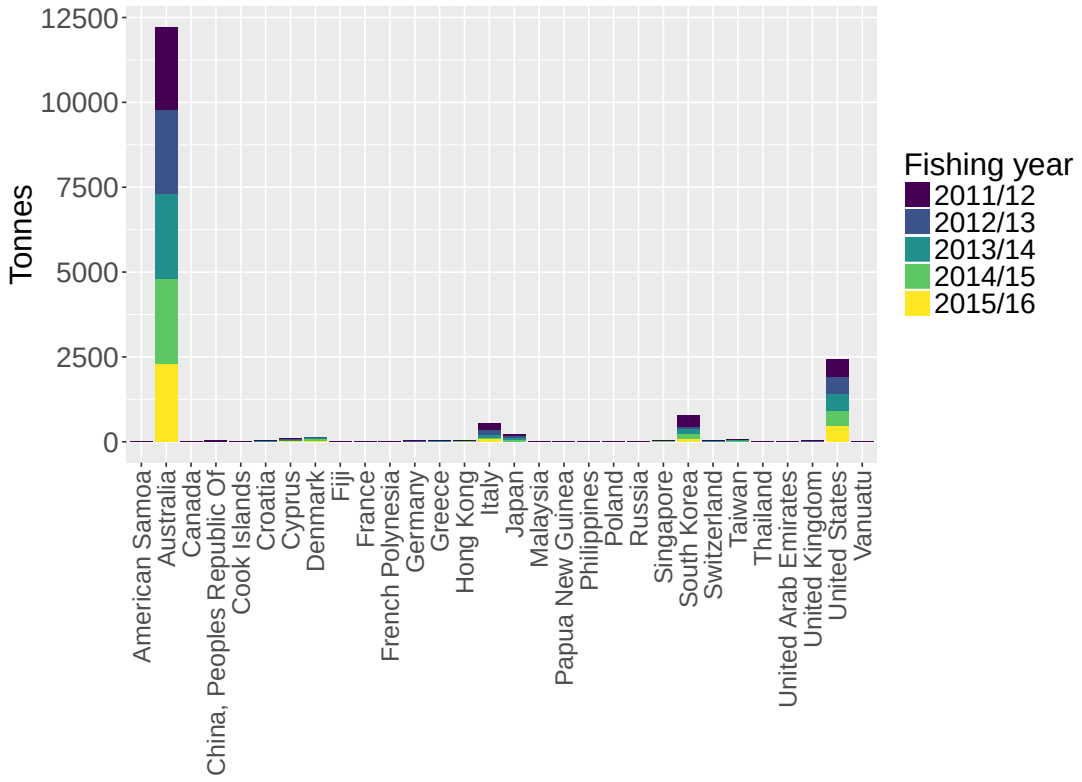

Figure 5: The destination of snapper exported whole (green) from New Zealand, by fishing year (Oct–Sept).

[4]Murray-Darling Basin Authority & Australian Government, Fish 'n' Chips, https://www.mdba.gov.au/sites/default/files/pubs/MDBA-13057-Fish-n-Chips-FS_web.pdf.

[5]The north-east Atlantic mackerel tagging programme has several similarities with the proposed snapper tagging programme, in particular that it focuses on stock assessment of a marine species with a relatively low mark rate and recovery of tags from commercial catches.

Scottish mackerel processors have recently become involved in scanning for PIT tags in mackerel, and do not have particular concerns around food safety. Fish are scanned as the whole catch passes over a conveyor prior to processing. Data from any tags detected are sent directly to a database and no attempt is made to find the fish and tag. Fish are gutted as part of the mackerel processing operation although this may be by a secondary processor. Secondary scanning for metal in the processed fish is carried out. Whole, ungutted fish may be supplied to consumers from the handline fishery. Shetland processors, who process the largest volume of mackerel, have only had one tag reported by a secondary customer (Steve Mackinson, Scottish Pelagic Fishermen's Association, pers. comm.).

Consequence: Negligible–Moderate, assuming adequate communication of risk management strategy to relevant stakeholders.

5.1.4 Reputational risks

Notwithstanding the fact that food processors are able to take a risk-based approach to managing the use of PIT tags in snapper, in much the same way that they would manage other potential foreign bodies such as hooks or packaging materials, there is the potential that consumers may still have concerns about the use of PIT tags. Concerns about glass in food have driven the development of plastic-encapsulated tags. Hallprint's marketing material[6] for 'food-safe' tags proposes that concerns about glass tags are self-evident:

> Hallprint's food-safe and external RFID PIT tags are already providing researchers with much needed peace of mind when tagging fish that could one day become food on the plate.
>
> Why expose your organisation to unacceptable risks of expensive litigation by implanting fish with glass capsule PIT tags?
>
> Any tagged fish that may enter the human food chain must remain safe to eat. Glass capsule tags are considered too risky to be used as implant tags for obvious reasons, so Hallprint will only provide food safe polymer capsule PIT tags for use in implanting fish that may one day be eaten.

The Australian Antarctic Division changed from using glass to plastic PIT tags in toothfish noting that some glass tags had been recovered from toothfish sold to Japanese restaurants;[7] however, toothfish have been tagged under the skin on the back of the head rather than in the body cavity (Welsford & Ziegler 2013).

The concerns about PIT tags entering the Japanese market appear to relate to PIT tags in general, rather than glass or plastic tags specifically. Harley et al. (2008) note that Japanese authorities 'strongly ask foreign countries not to use PIT tags for tunas, which have high potential to be imported to Japan', noting that tags would be considered extraneous substances that may injure consumers.

Inadequate communication to the customary and recreational sectors of steps taken or required to manage the food safety risks arising from the use of PIT tags would also exacerbate the reputational risks of the tagging programme.

The reputational risk, particularily in respect of export markets, will extend to all New Zealand snapper not just those caught from SNA 1.

Consequence: Moderate, based on the potential for social media to ignore risk management strategies.

[6] Hallprint, PIT Tags, https://www.hallprint.com/fish-tag-products/2014/8/26/pit-tags?rq=pit.

[7] Australian Fisheries Management Authority, Sub-Antarctic Resource Assessment Group (SARAG): Minutes SARAG 38, 16 March 2010, http://www.afma.gov.au/wp-content/uploads/2010/06/m20100316.pdf.

5.2 Acceptability of implantation site

The SNA 1 tagging programme proposes to mark fish by inserting PIT tags into the body cavity, as was the practice in the earlier SNA 8 programme. As noted above, insertion of tags into the body cavity is the practice in US salmon tagging programmes on the basis that this part of the animal is not used for human food. However, in contrast to the US salmon case, the sale of whole (green) snapper implies that the body cavity is regarded as 'food' for the purposes of the Food Act 2014.

The assumption that fish are always gutted before eating is not universally true. A number of fish species are cooked and/or consumed ungutted: this includes whitebait, small pelagics such as sardines and smelt, pacific saury (*Cololabis saira*) grilled whole in Japan,[8] and red mullet (*Mullus barbatus* and *Mullus surmuletus*).[9] However, there is no information (e.g., recipes published online) that suggests snapper would be cooked and consumed whole and ungutted. In contrast most 'whole fish' preparation instructions are clear that the fish is to be gutted.[10]

Major New Zealand processors and exporters of snapper were asked for information on sales of whole fish and when fish would be gutted. Feedback was received from Leigh Fisheries Ltd, Moana New Zealand and Sanford Ltd. It was considered that for fish sold whole in New Zealand the retailer would normally clean (gut) the fish, but that this service was on request and some cultures prefer to have the whole fish. Similarily, retailers in Australian and US markets will clean fish for customers, although it was noted that some chefs will purchase whole fish and clean these themselves rather than relying on fishmongers to do this. Snapper exports from New Zealand may go to wholesalers before being on-sold to the ultimate retailer of the fish, so a retailer or restaurateur cleaning a fish may not be a direct customer of the New Zealand fish processor.

Feedback from the Sydney Fish Market indicated that all of the retailers on their site display fish in a whole form but also offer a cleaning service to their customers, and that the same would apply with many of the (approximately 300) independent retailers who purchase whole fish via the Sydney Fish Market.

The choice of tag implantation site is linked to the wider risk management around the use of PIT tags: the legislative and reputational risks are as detailed above.

Consequence: Negligible–Moderate, assuming adequate communication of risk management strategy to relevant stakeholders.

5.3 Tag reaches plate and is identified

In the event that a PIT tag is undetected until it appears on the plate of a seafood consumer, but is detected by the person eating the fish, the key risk is to the reputation of the seafood processor.

To a large extent the reputational risks arising from PIT tags appearing in food are the same as any other foreign body, and should be managed in the same way. Analogous hazards are that fishing gear (e.g., longline hooks) or foreign objects from a processing factory (e.g., plastic packaging, fragments from overhead lights, etc.) remain in a product as far as a consumer's plate, or fish bones are left in a product that is sold as boneless.

Potentially, discovery of PIT tags used as a scientific research tool for supporting sustainable management of fisheries may be more acceptable to consumers than other foreign objects. However, a consumer finding a broken tag on their plate is likely to have concerns as to whether all pieces have been removed from the food.

[8] A Taste of Culture, A Fish Called Sanma, http://www.kibocooking.com/resources/files_pdf_documents/saltgrilled%20SANMA.pdf.

[9] Browne Trading Company, Red Mullet (Rouget), https://www.brownetrading.com/species-spotlight/red-mullet-rouget/; Great British Chefs, How to cook red mullet, http://www.greatbritishchefs.com/how-to-cook/how-to-cook-red-mullet.

[10] e.g., Sydney Fish Market, Whole Fish, http://www.sydneyfishmarket.com.au/seafood-school/recipes-cooking-info/recipes/cooking-style-details?id=33.

Reputational damage in the first instance will fall on the immediate seafood supplier, such as the restaurant where the consumer is dining or the fishmonger who sold it should the seafood be consumed at home. It is likely that this immediate supplier will wish to share any reputational damage with others in the supply chain, which could ultimately extend to the tagging programme as a whole.

Consequence: Negligible–Moderate.

5.4 Tag reaches plate and is not identified

In the event that a PIT tag is undetected through the processing and food preparation chain, then there is a risk that it will also be undetected by the seafood consumer and eaten. The key hazards in this circumstance relate to injuries to the consumer – these are considered below as separate hazards.

Clearly if a tag is eaten and causes injury then reputational damage to the relevant seafood supplier(s), and the tagging programme, is also likely. Where injuries result then liability for the harm caused may also arise. Just as reputational damage may be shared through the supply chain, insurers will seek to ensure that any liability for harm (and associated damages) is shared. All parties involved in the programme, from placing of tags to processing of fish for sale, will therefore need to ensure that they carry out their roles diligently.

Consequence: Extensive (based on maximum consequence rating of encountering a whole tag – choking).

5.5 Tag implantation into muscle rather than gut cavity

Implantation of tags into the body cavity is a key mitigation strategy to minimise the possibility that tags will reach a consumer's plate. While migration of tags from the body cavity of the fish is possible (e.g., Gheorghiu et al. 2010), the key hazard is considered to be that tags are not correctly placed. US researchers are periodically reminded of the importance of inserting tags into the correct site:

> The most important issue with PIT tag placement is human food safety. Tagging outside the abdominal cavity places the fish-consuming public at risk and jeopardizes the continued use of glass-encapsulated PIT tags for fisheries research. (PIT Tag Steering Committee 2015)

Documenting tagging procedures (e.g., PIT Tag Steering Committee 1999), training staff involved in tagging, and monitoring and auditing performance will be key strategies for ensuring tags are inserted into the correct location on a fish.

Consequence: Extensive (based on maximum consequence rating of encountering a whole tag – choking).

5.6 Implantation of undetectable tags

A hazard arises if tags are implanted that are not detectable by tag readers, as this increases the risk that tags will remain in fish products sold to consumers.

Properly applied PIT tags are considered to have very low failure rates (Gibbons & Andrews 2004) and are assumed to be reliable for the duration of the lifespan of the fish (Freeland & Fry 1995).

Mitigation of this hazard is possible by purchasing tags from a supplier with appropriate quality control procedures and ensuring that tagged fish are only returned to the sea after first ensuring that the implanted tag is readable.

Consequence: Extensive (based on maximum consequence rating of encountering a whole tag – choking).

5.7 Tag breaks during commercial processing

Breaking of tags during processing changes the nature of the hazard presented if tags are consumed. Breakage of glass-encapsulated tags produces pieces of glass with sharp edges, and both plastic and glass tags enclose electronic components that have sharper edges than the enclosing capsule.

Physical testing of tags (Appendix C) demonstrated that breaking strength of tags was related to encapsulation material and tag size. Larger glass tags were stronger than smaller glass tags, while the polymer-encapsulated tag was stronger than any of the glass tags tested. Furthermore, the polymer tag did not disintegrate after the initial brittle failure.

For tags correctly placed in the fish body cavity, the tag is unlikely to experience a direct pressure from a filleting knife during processing. However, where offal or damaged fish are used in fishmeal production, any undetected tags have the potential to be broken through contact with the augers or mills. Polymer-encapsulated tags have the potential to remain in larger pieces and be retained on screens. Metal tag components may be retained by magnetic screening while other components will be milled to small fragments.

Fragments of glass or metal between 7 mm and 25 mm in length in fishery products are considered 'adulterated' by the US Food and Drug Administration (USFDA 2011), who also note that foreign objects less than 7 mm length may cause trauma or serious injury to persons in special risk groups, such as infants, surgery patients and the elderly.

The temperatures used during the production of fishmeal are up to 95°C for up to 195 minutes (C. Webb, unpublished information from New Zealand-based seafood processors; FAO (1986)). The oven testing of tags (Appendix C) indicated that glass tags would be unaffected by this regime, but plastic tags may be distorted.

Consequence: Moderate (based on maximum consequence rating of swallowing a broken tag).

5.8 Tag breaks during food preparation

Breakage or disintegration of tags during food preparation changes the nature of the hazard presented if tags are consumed, generally producing sharper fragments.

For fish purchased whole, tags may be contacted by filleting knives during cleaning of the fish; however, for tags correctly placed in the fish body cavity, such contacts are likely to be a glancing contact of the tag by the blade rather than direct pressure causing breakage.

If a tag remains in a fish product during cooking, the possibility and mode of breakage depends on the tag type (see Appendix C):

- For oven cooking, glass tags remained intact at temperatures up to 250°C, but polymer used in plastic-encapsulated tags melted at 160°C. Plastic tags cooked at a lower temperature (110°C) for an extended period also distorted;
- However, glass tags break if subjected to extreme thermal shock. All three types of glass tags tested survived quenching from 175°C, but all the larger glass tags, and some of the smaller tags, broke when quenched from 250°C;
- Glass tags were unaffected by pressure cooking, but the envelope of the plastic tags tended to split or shrink;
- Plastics tags were melted by microwave cooking whereas glass tags became hot but remained intact.

Consequence: Moderate (based on maximum consequence rating of swallowing a broken tag).

5.9 Tag reaches consumer via a species other than snapper

There are two mechanisms by which a tag from the snapper tagging programme could reach a consumer through a species other than snapper:

- implantation of tags in a species other than snapper; and
- ecosystem processes, where a snapper is consumed by another species that is subsequently harvested for food.

The implantation of tags in species other than snapper is a hazard arising from the implementation of the programme, and is similar to the hazard that a tag could be placed in the wrong part of a snapper.

The ecosystem risk arises from the fact that tags placed in snapper may be consumed by other species and therefore enter the human food chain through those species instead. A striking example of this possibility is the recovery of a PIT tag, originally placed in a hatchery-bred steelhead trout (rainbow trout; *Oncorhynchus mykiss*) on the Columbia River in Washington State in September 2004, from a sooty shearwater chick harvested from one of the Titi Islands off Stewart Island.[11] The US National Oceanic and Atmospheric Administration considers that 'the most likely scenario is that the young salmon was caught and consumed by an adult sooty shearwater at the mouth of the Columbia River some time in the summer of 2005. The tag then remained in the bird's stomach for over 16 months until it was regurgitated to feed young chicks early in 2007.

Consequence: Moderate (based on maximum consequence rating of swallowing a broken tag).

5.10 Choking

Any PIT tags remaining in food present a choking hazard. Guidance for determining what constitutes a small part that presents a choking hazard is provided by 'AS/NZS ISO 8124.1:2013 Safety of toys – Part 1: Safety aspects related to mechanical and physical properties'. Section 5.2 of this standard defines small parts as those that fit in a cylinder of 31.7 mm diameter and a depth that tapers from 25.4 mm to 57.1 mm. All of the PIT tags considered here would constitute 'small parts' under this test, and therefore be considered a choking hazard for children.

Risk of choking is lower for adults, but the US Food and Drug Administration's 'Compliance Policy Guide on Foods – Adulteration Involving Hard or Sharp Foreign Objects' indicates that the presence of hard or sharp foreign objects that measure between 7 mm to 25 mm in length would be liable to seizure. In this case the specific harm referred to is tissue perforation and laceration, rather than choking.

Consequence: Extensive.

5.11 Biting tag

Biting down on a tag presents two specific hazards:

- damage to teeth;
- breaking the tag into fragments that cause damage to the tissues of the mouth.

Dental damage as a result of biting a glass PIT tag has been reported in the US (PIT Tag Steering Committee 2015):

> On July 9, 2015, PTAGIS was contacted by an individual who had bitten down on a PIT tag in a piece of smoked salmon and broke a tooth. This is the third known incident in less than two years of a human biting a PIT tag.

[11] PTAGIS, Titi recovery, http://php.ptagis.org/index.php/Titi_Recovery.

Physical testing (Appendix C) indicates that the breaking strength of small glass tags is much less than the maximum biting force of adults. The breaking strength of larger glass tags is just less than the maximal bite force, whereas the breaking point of polymer tags greatly exceeds this.

Consequence: Negligible.

5.12 Swallowing a tag whole

Whole tags have no sharp edges and are therefore unlikely to cause tissue damage. Ambe et al. (2012) note that in about 80% of cases of foreign-body ingestion, the ingested material passes uneventfully through the gastrointestinal tract.

Consequence: Insignificant.

5.13 Swallowing a broken tag

Broken tags, including damaged plastic tags where the components may be exposed, have sharp edges and may therefore cause damage to the gastrointestinal tract if swallowed. Sharp or pointed foreign bodies are likely to require emergency endoscopy procedures to remove the object from the upper gastrointestinal tract within 24 hours (Ambe et al. 2012). Over all foreign-body ingestions, the review by Ambe et al. (2012) indicated endoscopic intervention is required in 20% of cases and surgical intervention in less than 1% of cases.

Consequence: Moderate.

5.14 Toxins released by tag into food

The glass used for PIT tag encapsulation (at least by Biomark Inc.) is biologically inert (Appendix D). Physical testing (Appendix C) did not indicate any loss of weight when glass tags were heated.

Polymer-encapsulated tags use 'US FDA approved surgical plastics' (Frusher et al. 2009). When heated (Appendix C) the plastic tags lost weight, but regained this on extended exposure to the laboratory atmosphere suggesting the weight loss represented only moisture expulsion.

The PIT tag electronics include a number of heavy metals, including silver, aluminium, copper, lead, tin and zinc (McKenzie et al. 2006). However, these are entirely encapsulated by the glass or plastic casing.

Consequence: Insignificant.

6. EXPOSURE TO HAZARDS

Each hazard has been assigned a likelihood, using the descriptions contained in Table A-4 of Appendix A.

6.1 Evidence of food safety suitability

PIT tags in a food product represent a foreign object that would be considered to render the product unsuitable.

Likelihood: Almost certain (that there is a legislative or reputational hazard to be managed).

6.2 Acceptability of implantation site

In the last five years, an average of 52.8% of the TACC of commercially caught snapper was exported green. In these fish the body cavity is part of the traded food product and therefore within the scope of the Food Act 2014.

Likelihood: Almost certain (that there is a legislative or reputational hazard to be managed).

6.3 Tag reaches plate and is identified

Illustrations of the probability of a tag remaining undetected in a fish that is part of the commercial catch, based on a one-off tagging programme design with a single year of scanning for tags, demonstrates that the probability of a consumer encountering a tag in any given fish is less than 1 in 2500 (Appendix E).

The rate of fish with undetected tags (0.039%) compares favourably with the US Food and Drug Administration's Defect Action Level (levels of natural or unavoidable defects in foods that are presumed to present no health hazards for humans) for whole pits or pit fragments remaining in pitted olives of 1.3% (USFDA 1998). Alternatively, the CODEX standard for Quick Frozen Fish Fillets (Codex Alimentarius Commission 2014) considers a product defective if it contains more than one bone (greater or equal to 10 mm in length, or greater or equal to 1 mm in diameter) per kilogram of product.[12]

A consumer could consume more than 100 snapper a year before the annual probability of encountering a tag came close to the 5% threshold for 'rare' events. On the other hand, unless the entire commercial catch is scanned and the detection rate is 100%, it is certain that undetected tags will be present in fish sold as food. For the design illustrated in Appendix E, several thousand undetected tags will enter the food trade.

Although a significant part of the commercial catch of snapper is exported whole and ungutted, there is no evidence that snapper are routinely consumed whole. Thus the probability that tags remain in snapper that are properly tagged in the body cavity and cleaned prior to cooking is a function of the failure rates in these processes. There is no known data available to allow these rates to be quantified, but an appropriate experiment would be relatively straightforward.

It is likely that the probability that a seafood processer, or cook, fails to notice a PIT tag remaining in the body cavity of a fish is related to the state to which the fish is prepared, and to the size and colour of a tag. Residual tags will be more readily apparent in fish prepared to a fillet state than in fish that are simply gutted for cooking whole. Snapper flesh is light coloured, so the darker tags (e.g., tags B–E in Figure 3) should be more easily spotted than the white plastic-encapsulated tag A. If tag visibility is assumed to be related to tag volume then the larger PIT tags are 4 to 6 times more visible than smaller tags (Table 2).

Table 2: Relative tag visibility for tags tested in Appendix C.

Tag type	Length (mm)	Diameter (mm)	Volume (mm^3)	Relative visibility
Biomark HPT23	22.0	4.0	276.46	100%
Biomark HPT12	12.6	2.1	43.64	15.8%
SwissPlus Polymer	11.0	2.7	62.98	22.8%

Likelihood: Rare (that an undetected tag is encountered by an individual consumer); Possible (that an undetected tag is not spotted and removed during fish processing and preparation).

[12] While the comparison with permissible rates of residual fish bones is instructive, it should be noted that under this CODEX standard, PIT tags would be considered foreign matter, and there is a zero tolerance for any such material that 'indicates non-compliance with good manufacturing and sanitation practices'.

6.4 Tag reaches plate and is not identified

The final seafood consumer provides a further opportunity for tags to be identified before consumption. Relative probability of detection will be greater for larger tags (Table 2).

Likelihood: Unlikely (that an undetected tag is not spotted and removed during fish processing and preparation, and is not spotted by the seafood consumer).

6.5 Tag implantation into muscle rather than gut cavity

Evidence from US salmon tagging programmes shows that occasional tags are encountered by consumers that are assumed to have been incorrectly located in the flesh rather than the body cavity of the fish (PIT Tag Steering Committee 2015). Two New Zealand companies processing fish from aquaculture facilities have noted that tags are recovered from the body wall, and that this could be due to difficulty in always implanting tags into the body cavity of the fish (Tom Searle, Peter Buxton, pers. comm.).

From tests of plastic-encapsulated PIT tags in snapper, McKenzie et al. (2006) indicated that smaller (12 mm) tags were more likely to migrate from the tagging site and lodge in the gonad or embed in the peritoneum (the lining of the abdominal cavity) than the larger (23 mm) tags.

Likelihood: Likely.

6.6 Implantation of undetectable tags

Assuming that tags are purchased from a reliable vendor with good quality control, and tagged fish are scanned before return to the sea, then the likelihood of undetectable tags being placed into snapper will be low.

Likelihood: Rare.

6.7 Tag breaks during commercial processing

The fact that an average of 52.8% of the TACC of snapper[13] was exported green in the last five years has the effect of reducing the opportunity for undetected tags to be broken during commercial processing. No data are available on the forces that could be applied to tags during gutting or filleting, but tags in the body cavity will not generally be subject to direct pressure from a knife blade in this process.

Tag breakage during processing of offal to fishmeal is more likely. The volume of snapper product being used in fishmeal production is unknown.

Likelihood: Unlikely (that an undetected tag is broken during commercial processing); Likely (that an undetected tag is broken if present in product sent for fishmeal processing).

6.8 Tag breaks during food preparation

Given the proportion of snapper exported green, undetected tags will have a greater exposure to the risk of breakage during preparation in a domestic or restaurant kitchen than in a commercial processing facility. However, forces applied to tags during such processing are likely to be lower than in commercial processing due to reduced use of machinery.

Likelihood: Unlikely (that an undetected tag is broken during food preparation).

[13] Noting that this is based on all New Zealand snapper, not just SNA 1.

6.9 Tag reaches consumer via a species other than snapper

Implanting a tag in a species other than snapper is analagous to the risk of placing a tag into the wrong part of a snapper and is therefore considered to have a similar likelihood of occurence.

Snapper are generalist predators, and the importance of snapper as a food source for other predators is considered to be poorly understood (Ministry for Primary Industries 2016). It has been suggested that adult snapper have few predators other than humans, but that juveniles are prey for birds, sharks, John dory, kahawai and adult snapper.[14] Pinkerton et al. (2015) indicate predation on snapper by cetaceans, sharks and birds, while MacDiarmid et al. (2016) suggest that, historically, hāpuku on coastal reefs probably preyed upon snapper of less than 400 mm total length.

Noting that the selectivity of the longline method proposed for use in tagging snapper will not typically catch juvenile snapper, it is unlikely that there will be significant predation on tagged snapper by species that are subsequently harvested for food. Any tags consumed by snapper predators are likely to remain in the gastrointestinal tract. Food processors may be less aware of the potential for PIT tags to occur within species other than snapper.

Likelihood: Rare (of implantation in a species other than snapper, assuming that appropriate tagging protocols are in place and adhered to); Rare (that a tag reaches a consumer through a species that predated on snapper).

6.10 Choking, biting, or swallowing tag

The probabilities that a tag chokes a consumer, or that it is bitten or swallowed, conditional on an un-detected tag being placed in a consumer's mouth, will be size dependent (see Table 2).

Although all PIT tags are a choking hazard, according to 'small parts' standards, it is likely that the larger tags present a greater likelihood of choking. However, because they are more noticeable in a mouthful of food, larger tags are anticipated to have a lower likelihood of being bitten or swallowed.

Tags in salmon have reportedly been bitten by consumers (PIT Tag Steering Committee 2015).

Likelihood: Possible (that an undetected tag causes choking, is bitten or swallowed).

6.11 Toxins released by tag into food

No circumstances are apparent where PIT tags for use in tagging fish could release toxins into the fish. In tests of plastic-encapsulated PIT tags, McKenzie et al. (2006) found no significant difference in levels of silver, aluminium, copper, lead, tin and zinc between tagged and control fish over a three-month period.

No glass- or plastic-encapsulated tags subjected to pressures of 20 or 40 atmospheres and exposed to 'a cocktail of isotonic fluids and fish oils designed to replicate the chemical effects of body fluids' failed, and, although some delamination of the acrylic shell of the plastic-encapsulated tags was noted after variable pressure exposure, no breach of the underlying epoxy medium occurred (McKenzie et al. 2006).

Likelihood: Rare.

[14] Department of Conservation & Ministry of Fisheries, Harbours, bays and estuaries –- at the edges of land and sea, http://www.doc.govt.nz/Documents/getting-involved/students-and-teachers/themes/estuaries/snapper-education-resource.pdf

7. ESTIMATION OF RISKS

Combining the consequence and likelihood estimates, presented in the preceding sections, for the various hazards posed by tagging of snapper, results in the overall risk estimates in Table 3. Note that if a range of estimates arose in the hazard characterisation and exposure assessments, the highest rating was used to derive the risk category.

Table 3: Risk estimates for hazards arising from the use of PIT tags in the SNA 1 tagging programme.

Classification	Hazard	Likelihood	Consequence	Risk Rating
Governance	Evidence of food safety suitability	Almost certain	Moderate	High - 8
	Acceptability of implantation site	Almost certain	Moderate	High - 8
Process	Tag reaches plate and is identified	Possible	Moderate	Medium - 6
	Tag reaches plate and is not identified	Unlikely	Extensive	Medium - 6
	Tag implantation into muscle rather than gut cavity	Likely	Extensive	High - 8
	Implantation of undetectable tags	Rare	Extensive	Low - 5
	Tag breaks during commercial processing	Likely	Moderate	High - 7
	Tag breaks during food preparation	Unlikely	Moderate	Low - 5
	Tag reaches consumer via a species other than snapper	Rare	Moderate	Low - 4
Physical	Choking	Possible	Extensive	High - 7
	Biting tag	Possible	Negligible	Low - 5
	Swallowing tag whole	Possible	Insignificant	Low - 4
	Swallowing broken tag	Possible	Moderate	Medium - 6
Biological	Toxins released by tag into food	Rare	Insignificant	Very low - 2

8. DISCUSSION

Five High risks from the use of PIT tags in an SNA 1 mark-recapture programme are identified (Table 3):

- In the case of Governance hazards, the risk ratings highlight the need for risk management planning to be put in place by food processors to avoid legislative exposure or reputational harm.
- The High risk rating in the case of commercial processing arises due to fishmeal production. Exposure in this case is not well characterised as the extent to which snapper is used in fishmeal is not documented.
- Information from processors on the frequency with which tags are found in the body wall of processed fish tagged in aquaculture operations indicates that there is a High risk of tags being implanted in the gut wall rather than the gut cavity.
- The highest risk rating to seafood consumers arises from the risk of choking, as this is the only injury where death is a potential outcome.

The hazards identified are not independent. The risk that a tag reaches a consumer's plate and is not identified represents the best overall summary on risk of consumer harm because the consequence rating given is the highest consequence arising from the individual injury hazards, and the exposure risk would naturally include risks of poorly implanted or undetectable ('dud') tags.

From the perspective of individual consumers, risks posed by the tagging programme are low as encounter rates with tags will be low – much lower than typical defect levels for unexpected items in some other food products.

However, the fact that – under the proposed design – reasonably large numbers of undetected tags will remain in the commercial catch emphasises the importance of detecting and removing these tags in order to avoid a potential harm from the use of PIT tags. That some tags will not be detected is inevitable when not all catch that could include tags is scanned. High rates of detection and/or removal of tags when fish are prepared for eating is therefore important. The estimated likelihood for this process is not well informed by data, and the judgement that tags are unlikely to reach a consumer's plate, and not be identified, is uncertain. Thus the detectability of the chosen tag type before and during processing is extremely important.

Once a preferred tag is selected, experimental approaches could be used to refine/confirm a number of the estimates in this document:

- the rate at which tags are incorrectly implanted by trained staff into the flesh of the fish;
- the probability of tags not being removed during evisceration and not being spotted by processing staff or those involved in food preparation;
- the proportion of tags broken when fish are gutted.

Because tag detectability is influenced by tag size, the uncertainty in the extent to which tag size influences choking risk must also be highlighted.

The currently favoured design for a SNA 1 tagging programme envisages three years of tag releases and scanning for recaptures ('the triplet design'). The design choices have been focused on efficiently meeting the required precision on estimates of abundance and movement between areas. It should be noted that the food safety hazards resulting from the programme would persist after the planned recapture phase has been completed, because it is not anticipated that all tagged fish will have been recaptured (or died) within three years. As a result, management of the food safety hazards arising from the programme should continue following the completion of the stock assessment focused parts of the programme. The

risk decreases over time, but tagged fish will be present in commercial catches for 20–30 years after the programme is completed.

It would be valuable if the food safety risk management process established for the SNA 1 tagging programme included a monitoring component that ensured the collation of data relating to any food safety issues that eventuate as a result of the programme. Such information is only anecdotally available from the previous SNA 8 programme: for example, a tag from the SNA 8 programme recovered in February 2017 came to light through a Facebook post (Shelton Harley, MPI, pers. comm.).

9. ACKNOWLEDGEMENTS

This work was completed under Ministry for Primary Industries contract SEA2016-31: Food Safety Testing of PIT tags for SNA 1 tagging programme.

Martin Ryan of Callaghan Innovation completed the physical testing of tags reported in Appendix C. Alison Undorf-Lay and Peter Buxton (Sanford Ltd), Tom Searle (Leigh Fisheries Ltd), Mark Preece (New Zealand King Salmon Ltd), Nathan Reid (Moana New Zealand), and Dave McQueen (NIWA) generously provided information on snapper markets and/or use of PIT tags in New Zealand that assisted in the risk scoring. Hallgeir Jørmeland (RFID Solutions) and Aril Slotte (IMR) kindly answered email queries about the NEA mackerel tagging programme, and Steve Mackinson and Aoife Martin assisted in obtaining information from Scottish mackerel processors.

Feedback from Judy Barker, Lisa Olsen, Shelton Harley, Marc Griffiths, Steve Halley, John Taunton-Clark, and Robert Gear (all Ministry for Primary Industries) and Richard O'Driscoll (NIWA) on various draft documents has assisted in finalising this report. Review of the draft FAR by John Taunton-Clark is appreciated. Dragonfly Data Science provided the LaTeX template used for this report, and Barbara Graham provided valuable editorial advice.

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APPENDIX A: RISK MATRIX AND CATEGORY DESCRIPTIONS

The qualitative risk assessment methods employed in this report result in risk estimates (Table A-1) that are based on the consequence (Table A-3) and likelihood (Table A-4) associated with a particular hazard. The specific risk matrix and descriptors used here follow Talbot (2011).

Table A-1: ISO 31000 risk matrix.

		Consequence				
		1 - Insignificant	2 - Negligible	3 - Moderate	4 - Extensive	5 - Significant
Likelihood	E - Almost certain	6	7	8	9	10
	D - Likely	5	6	7	8	9
	C - Possible	4	5	6	7	8
	B - Unlikely	3	4	5	6	7
	A - Rare	2	3	4	5	6

Table A-2: Risk categories and risk management approach implied.

Category	Risk management approach
Very low	Managed by routine procedures.
Low	Monitor and manage by routine procedures.
Medium	Management responsibility must be specified.
High	High risk, senior management attention required.
Very high	Immediate action required by the Executive with detailed planning, allocation of resources and regular monitoring.

Table A-3: Consequence descriptors for injuries (people) and reputational hazards.

Category	People	Reputation
Insignificant	Minor injury or first aid treatment	Local mention only. Quickly forgotten. Freedom to operate unaffected. Self-improvement review required.
Negligible	Injury requiring treatment by medical practitioner	Scrutiny by Executive, internal committees or internal audit to prevent escalation. Short term local media concern. Some impact on local-level activities.
Moderate	Major injury / hospitalisation	Persistent national concern. Scrutiny required by external agencies. Long-term 'brand' impact.
Extensive	Single death and/or multiple major injuries	Persistent intense national public, political and media scrutiny. Long term 'brand' impact. Major operations severely restricted.
Significant	Multiple deaths	International concern, Governmental Inquiry or sustained adverse national/international media. 'Brand' significantly affects organisational abilities.

Table A-4: Likelihood descriptors for hazards.

Category	Chance	Frequency	Probability
Rare	May occur only in exceptional circumstances	Has occurred or can reasonably be considered to occur only a few times in 100 years.	<5%
Unlikely	Could occur at some time	Has occurred 2 or 3 times over 10 years in this organisation or similar organisations.	<35%
Possible	Might occur at some time	Has occurred in this organisation more than 3 times in the past 10 years or occurs regularly in similar organisations or is considered to have a reasonable likelihood of occurring in the next few years.	>35%
Likely	Will probably occur in most circumstances	Occurred more than 7 times over 10 years in this organisation or in other similar organisations or circumstances are such that it is likely to happen in the next few years.	>65%
Almost certain	Is expected to occur in most circumstances	Has occurred 9 or 10 times in the past 10 years in this organisation or circumstances are in train that will almost certainly cause it to happen.	>95%

APPENDIX B: USFDA LETTER ON PIT TAG FOOD SAFETY

Biomark have supplied the following letter, dated 1998, in support of their statement regarding US government agency approval for use of PIT tags.

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
Rockville MD 20857

IFA 9893-G-0001

Mr. Kevin Nieuwsma
Director Strategic Development
490 Vilaume Avenue
South St. Paul, Minnesota

Dear Mr. Nieuwsma:

We refer to your submission dated December 22, 1997, concerning the use of the Destron Fearing Model TX 1400L glass transponder for the identification of fish (salmon).

There is no human food safety concern for the use of the TX 1400L transponder in salmon, provided that the portion of the animal containing the implanted device will not be used for human food.

In light of these findings, we do not now plan to recommend or initiate any enforcement actions against the use of the Destron Fearing Model TX 1400L transponder in salmon provided: the transponder does not remain in edible portions of the animal after slaughter; the transponder is used for the sole purpose of animal identification; the labeling and advertisements or other sources of information are not false or misleading in any particular; and we do not receive new data raising questions regarding the safety of the product. This is also done with the understanding that your firm will obtain concurrence from U.S. Department of Agriculture (USDA) as to the acceptability of the implantation site(s). Please copy my office on all correspondence with USDA on this matter.

If you have questions concerning this letter, please contact Dr. John P. Machado. He can be reached by telephone at (301) 827-0281. When inquiring about this matter, please refer to IFA 9893.

Sincerely yours,

George Graber, Ph.D.
Director
Division of Animal Feeds
Center for Veterinary Medicine

cc:
Dr. William James, USDA/FSIS
Dr. William Leese, USDA/FSIS

APPENDIX C: PHYSICAL TESTING OF TAGS

Callaghan Innovation carried out testing of tags to determine their physical performance under various conditions related to the processing, preparation and consumption of seafood.

CallaghanInnovation

File No: 93262230

16 June 2017

Dr D Middleton
Trident Systems
PO Box 297
Wellington 6140

Dear David

Testing of RFID Tags for Fish

We received from you 118 specimens comprising four different Radio Frequency Identification "tags" under consideration for use in monitoring fish behaviour in the wild, and registered them with our job identification 93262230. You had previously left with us a few examples of the same or similar products for inspection.

The tags are to be inserted in the body cavities of species that are caught commercially, so there is concern that the tags could remain in fish processed and/or sold for food products, creating a hazard for the consumer. You requested testing of the tag samples for:

- Breaking strength
- Response to oven heating (110 degrees Celsius)
- Response to thermal shock
- Response to pressure cooking (autogenous steam pressure at 134 degrees Celsius)
- Response to microwave heating

Figure 1 Tag Samples for Tests

Left: *Biomark HPT23, a 4 mm diameter 22 mm long glass envelope tag*
Left centre: *Biomark HPT12, a 2.1 mm diameter 12.6 mm long glass envelope tag*
Right centre: *SwissPlus ID Bioglass, a glass envelope tag similar to the HPT12*
Right: *SwissPlus ID Bio Polymer, a 2.7 mm diameter 11 mm long plastic tag*

callaghaninnovation.govt.nz
0800 4 CALLAGHAN (0800 422 552)

The samples comprised a large glass envelope type, near-identical small glass envelope types from two different suppliers and a small plastic envelope type, illustrated in the figure above.

It was noted that a few of the plastic tags had different coloured envelopes, suggesting that they had come from a batch different from the majority (measurement of dimension and mass reinforces this suggestion). Further, the number of plastic tags was two fewer than required, so two of the initial inspection specimens were added to the sample for oven testing, raising the possibility that these also were from a different manufacturing batch.

Sample batches of six specimens of each type of tag were subjected to each of the tests. Fresh specimens were generally used for each test, but in the case of the thermal shock test uncertainty about the temperature of the initial test meant that a repeat test was performed on specimens that had previously been subjected to the oven-heating test.

1. Breaking Strength Test

Tags were tested in diametral compression between cemented carbide platens on an Instron 1126 universal testing machine equipped with 250 kN load cell. Crosshead speed during the test was 0.5 mm per minute.

This test configuration induces *tensile* stress in the interior surface of the glass cylinder; it is not a crushing test. Stress will reach a maximum (where failure will initiate) adjacent to the load points. As glass is weaker in tension than in compression, this test will return a conservative value for failure load.

The glass envelope tags all exhibited brittle failure which destroyed their integrity; the plastic envelope tags initially suffered brittle failure which is reported as the end-point of the test, but subsequent behaviour was plastic so disintegration was not immediate. A second HPT23 test was performed on the autoclave test sample, as a check on post-autoclave integrity – results were not significantly different from the initial test results.

Sample	Failure Load/N
Biomark HPT23	326 (75), 324 (39) *
Biomark HPT12	92 (33)
SwissPlus ID Bioglass	69 (15)
SwissPlus ID Bio polymer	805 (447)

Format is mean (standard deviation)
* Second test is from the autoclave set

As context for these results, consider that Rosa et al in Open Journal of Stomatology, 2012, 2, 21-26 [OJST http://dx.doi.org/10.4236/ojst.2012.21004 Published Online March 2012 (http://www.SciRP.org/journal/ojst/)] found that mean maximal bite force in the molar region for their (small!) control group of adults was 350 ± 54 N on the right side and 388 ± 80 N on left side.

2. Oven Test

Tags were tested by exposure to 110 °C air for 270 minutes in a laboratory oven. They were visually examined for signs of failure, and weighed before and after test to establish whether outgassing had occurred or not.

The glass envelope tags were unaffected by the test exposure, and only non-significant mass changes of less than 0.1 mass percent were recorded.

The plastic envelope tags however exhibited slight distortion, and a short-term mass loss of 0.36% (0.07%) on average. This was fully recovered on extended exposure to the laboratory atmosphere, suggesting that the loss was due to moisture expulsion only.

Sample	Mass Loss / %	Final Mass Loss / %
Biomark HPT23	0.00 (0.01)	-
Biomark HPT12	-0.07 (0.04)	-
SwissPlus ID Bioglass	-0.05 (0.09)	-
SwissPlus ID Bio polymer	0.36 (0.07)	0.07 (0.09)

Format is mean (standard deviation). Negative values denote mass gain.

The glass tags from this test were subsequently subjected to a thermal shock test.

3. Thermal Shock Test

Tags were tested by equilibrating them at the chosen temperature in air in a vertical tube furnace, then dropping them into water at room temperature. The number of failed specimens was counted as the test measure.

The initial test was carried out by quenching from 250 °C, but the hold temperature was uncertain (it may have exceeded 250 °C, although subsequent testing suggests that it was not significantly higher). The glass tags used for the oven test were therefore subjected to (a) a quench from 175 °C (which all survived), then (b) a quench from 250 °C.

Failures were catastrophic, with the seal end of the envelope typically detaching and the cylindrical portion splitting axially. See Figure 3, appended.

The plastic tags were not retested, as the initial set melted and foamed. Infrared spectroscopy of the envelope material suggests that it is polymethyl methacrylate with a melting temperature of about 160 °C.

Sample	Number of failures (of six)		
Quenched from:	Initial 250°C	Final 175°C	Final 250°C
Biomark HPT23	6	0	6
Biomark HPT12	0	0	2
SwissPlus ID Bioglass	1	0	0
SwissPlus ID Bio polymer	6 (melted)	-	-

Specimens for "Final" test had already been tested (without quench) at 110 °C.

It is evident that quenching from 250 °C induces failure in the glass tags to a high degree of probability.

4. Autoclave Test

Tags were tested by sealing in a closed steel vessel half filled with water, and heating to 134 °C for 1 hour duration. Equilibrium steam pressure at this temperature is 3 bar absolute (2 bar gauge). The tags were immersed in the liquid phase during their exposure. Visual inspection was undertaken, and mass gain was monitored as the test measurement.

Sample	Mass gain / %
Biomark HPT23	0.01 (0.01)
Biomark HPT12	0.03 (0.05)
SwissPlus ID Bioglass	0.02 (0.04)
SwissPlus ID Bio polymer	1.31 (0.06)

Format is mean (standard deviation).

The glass tags are unaffected by this test, exhibiting only non-significant mass gains and no observable post-test differences.

The plastic tags' envelopes opacified, and tended to split and or shrink, especially at the seal (open) end, exposing the potting compound. See Figure 4, appended. On average, a mass gain of 1.3 % occurred.

5. Microwave Heating Test

Tags were tested by placing in a domestic microwave oven of 1100 W power, and heating on full power for a measured duration.

Initially, the tags were exposed in zip-lock polythene bags but a two-minute exposure was sufficient to raise the temperature to the point where the bag melted. The tags were then removed from the bags and exposed for a further three minutes in a ceramic dish, at which time the test was halted as the plastic tags had been destroyed and were on the verge of melting. See Figure 5, appended.

Glass tags heated also, but did not suffer any ill effects.

Sample	Response
Biomark HPT23	Heated
Biomark HPT12	Heated
SwissPlus ID Bioglass	Heated
SwissPlus ID Bio polymer	Heated, ruptured and distorted, pre-melting behaviour

The ferrite rod and copper winding contained in the tags acts as a susceptor for the microwaves, continuing to heat as long as the presence of microwave radiation is maintained. This heating mechanism is not self-limiting, as it does not rely on the presence of water. Ultimately, it is probable that the glass tag envelopes would have heated sufficiently to melt.

Yours sincerely

M Ryan
Scientist
Advanced Materials Group
Martin.Ryan@callaghaninnovation.govt.nz

C D Lendrum
Group Manager
Advanced Materials Group
Conrad.Lendrum@callaghaninnovation.govt.nz

Figure 2 *Result of Crushing Test*

Left: *SwissPlus ID BioGlass 12mm*

Centre: *Biomark HPT23*

Right: *SwissPlus ID Bio Polymer 11mm*

The test was diametral compression between hardmetal platens in a universal testing machine, with crosshead travelling at 0.5 mm per minute. With this testing configuration initial failure is tensile, at the inner surface of the envelope.

Typically, the non-potted end (which was also the seal end) separated from the glass tags – but in all cases a network of cracks was observed throughout the glass envelopes after testing.

The plastic tags suffered axial cracking, just visible in the photograph. After initial failure the tags responded plastically.

Figure 3 *Result of Thermal Shock Test*

Left: *Biomark HPT23*

Right: *SwissPlus ID BioGlass 12mm*

All glass tags survived quenching from 175 ^{0}C into room temperature water.

All HPT23 tags failed upon quenching from 250 ^{0}C into room temperature water, with separation of the seal end and axial cracking. The experiment was repeated with identical results.

Most 12mm tags survived quenching from 250 ^{0}C into room temperature water – one SwissPlus ID tag failed as shown (from two batches of 6 specimens) and two Biomark HPT12 tags failed in similar manner (both from one of two batches of 6 specimens).

The plastic tags were not tested as the envelope polymer melts at about 160 ^{0}C.

Figure 4 Result of Autoclave Test

SwissPlus ID Bio Polymer 11mm. Note the "odd man out" uncoloured tag.

The test was an hour of exposure to 3 bar (absolute) steam pressure at 134 ^{0}C, during which the tags were immersed in liquid water.

Plastic tags became opacified, and showed envelope shrinkage and splitting, with tendency to extrude the potting compound from the seal end. There was a slight (~1%) weight gain.

All glass tags remained unaffected by the test.

Figure 5 *Result of Microwave Heating Test*

SwissPlus ID Bio Polymer 11mm. Note the "odd man out" uncoloured tag.

The test was 2 minutes' exposure to microwave heating in a 1100W domestic microwave oven, followed by a further 3 minutes of exposure.

The plastic tags all suffered envelope rupture and distortion to a greater or lesser degree. The local temperature approached the melting point of the polymer material.

The glass tags all got hot during the test, but suffered no consequences as the test was halted sufficiently early.

Note that if the tags (plastic or glass) remain in the oven while it is energised they will continue to heat, to the point where even the glass envelopes will melt. The ferrite core with winding is a susceptor; no moisture need be present.

APPENDIX D: BIOGLASS ASSESSMENT

Biomark have supplied the following information on the glass used for tag encapsulation.

Glass 8625 (Bioglass)

Certificate of AECO of 1990/09/04 about the suitability of 8625 for the encapsulation of animal identification systems.

ELG/Da
Dec. 02. 1999

SCHOTT
TOTAL CUSTOMER CARE

- Englisch - ÜBERSETZUNG für: OLE/Dtz

Bioglass

AECO

Arbeitsgemeinschaft für EDV-gestütztes
Controlling und Organisation (GBR)

prepared on Sept. 4, 1990

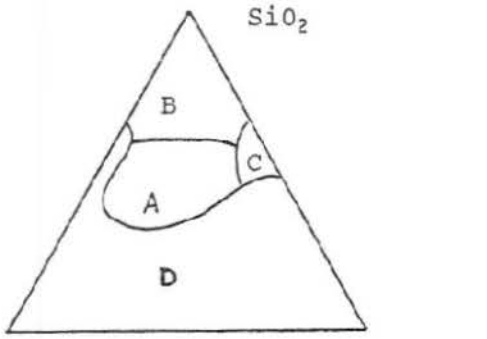
BIOGLASS

(Tissue-compatible glass of the infrared-sealing type for encapsulation of animal implants.)

Application: The bioglass is provided as a cladding material for subcutaneously implantable identification systems, transmitters, microchips, etc. on animals.

Specification: The chemical composition as well as the physicochemical properties of the product mentioned - hereinafter called "Schott Bioglass" - are listed in the Annex. In accordance with a classification system for bioglasses and bioceramics according to Hench and Wilson (1984), the product in question is to be classified, due to its composition, into the silicon sodium group. This corresponds, in the following figure 1, to area 'B'.

Fig. 1



A = Bone-bonding
B = Fibrous tissue encapsulation
C = Leaching (solubility)
D = Not glass-forming

Of quantitative significance are: calcium, potassium, magnesium, iron and aluminum. In smaller quantities (1 % and less) are contained barium and boron. Halogen salts as well as other compounds (such as titanium dioxide) are detectable in traces only. It can be compared with a bioglass type already admitted in the U.S.A. (Schott, 1990).

Tissue compatibility of bioglasses.

Since 1969 have increasingly been used bioglasses, glass-ceramic and ceramic articles as implants in orthopedic, otolaryngologic, dental and maxillofacial surgery. More recently, these products were also used, as mentioned already, as a protective sheath of functional implants. The selection of the glass or ceramic type depends essentially on whether the implant is subject to mechanical stresses (e.g. artificial hip) or not (e.g. otolaryngologic), in both cases, however, on whether there is a bond with the surrounding tissue (Gross and Strunz, 1985; Thieme et al., 1982; Schepers et al., 1989), or whether, as in the case of implant encapsulation, a bond of the encapsulated material shall more or less be prevented (Ball et al., 1988; Blencke et al., 1975).

In the first case, a partial, intermittent exchange of materials is desirable in order to obtain a physicochemical bond of the implant with the tissue (bone substitute or implant). In the second case, the cladding shall prove to be nearly insoluble for being able to maintain the protection of the actual implant over the lifetime of the animal. Therefrom result two nexus of problems which are of relevance with regard to toxicity:

1) Toxic, especially yatrogenic, action of the implant in the tissue as a whole (repulsive reactions, inflammation processes, formation of fibrotic, necrotizing tissue up to proliferative cell growth - preliminary stage of potential cancerogenity).

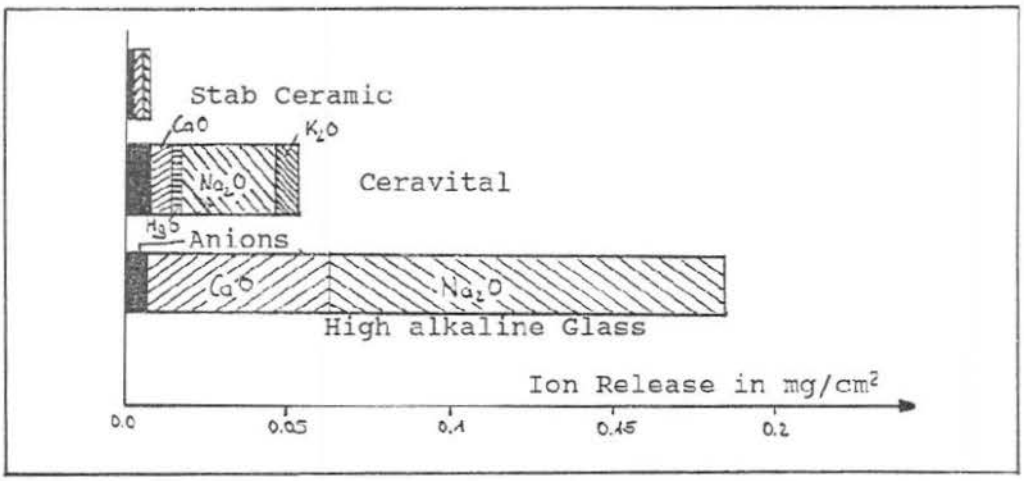
2) As a function of the leaching processes, removal of individual components from the cladding material, which may then become reactive (systemically toxic as well as effects as stated under 1).

Re: 1)

For testing the tissue compatibility of glass-cladded microchips as an animal identification system, these chips were encapsulated in glass into 55 male and 55 female Sprague-Dawley rats, cold--sterilized, implanted subcutaneously, and the animals were kept over 105 weeks. Of the animals kept separately were recorded weekly symptomatology, development of body weight and palpation findings, and monthly the food consumption. 5 animals each per sex were dissected 2, 12 and 28 weeks respectively after implantation (p.i.), and tissue for the histopathological examination was taken from the point of implantation. The implant of one animal per sex was checked for substantial structural changes by means of the SEM method (scanning electron microscopy). The remaining animals were examined in the same manner 52 and 105 weeks p.i.

The result showed that appearance and behaviour, development of body weight and food consumption of the animals were not impaired by the implant. Palpable tissue proliferations could not be detected in the points of implantation. From the histopathological point of view, the implanted chips were surrounded by a thin fringe of connective-tissue fibers only. There were no indications of acute or chronic inflammation reactions and of any marked connective-tissue encapsulation. The investigation of the implantation material by means of the SEM method did not show any changes. The authors concluded from this that such implants are suitable for animal identification for long-time applications (Ball et al., 1988). This is in agreement with the model according to Hench and Wilson (fig. 1). Schott Bioglass as well as the glass described herein show a relatively high percentage of silicon oxide (> 65 %), which indicates a high degree of cross-linking and a distinctly reduced solubility resulting therefrom (Ducheyne, 1985). However, for any kind of bonding, a minimum of solubility is necessary as an efficient bond is founded on a physicochemical basis. The solubility grows with an increasing percentage of alkali oxides (e.g. sodium oxide) in substitution for silicon oxide, for instance, as shown in the following figure 2:

Fig. 2: Solubility of different bioactive implant materials in neutral immersion.



The soft-tissue compatibility of glass-ceramic implants which, in their composition, are comparable with the bioglasses, could already be shown by Blencke et al. (1975). The material was implanted in rats, either intramuscularly, subcutaneously or intraperitoneally, and the reaction of the particular tissue was observed over a period of 60 weeks. Implants of diameters > 250 micrometers were well compatible and surrounded only by a dense, however, narrow layer of fibrous tissue. Repulsive reactions were missing. In the beginning, the inflammatory reactions were slightly stronger as compared to oxide-ceramic materials. After formation of a silicon gel layer on the implant surface, the reactions quieted down; the cell structures were then regular, and there were no atypisms. In smaller particle sizes, reactions were identified as are also observed in small particles of other materials (e.g. polyethylene), and they were, therefore, classified as independent of materials.

In further investigations on rats, rabbits and German shepherd dogs, in the tibia and the femur of whom had been implanted glass--ceramic specimens, it could be shown that the material displayed no substantial disintegration, which suggests perfect biocompatibility as well as an adequate lifetime for the application as an implant (Blencke et al., 1978).

The dependence of the solubility on the composition (silicon oxide/sodium oxide ratio) could be shown also by papers of Pernot and Zarzycki (1985) on rats. Implants with a sodium content of 33.3 % (silicon content 66.6 %) were inserted in rats over 8 to 60 days. Diffraction measurements (X-ray) and electron-microscope examinations indicated obvious corrosions as compared to implantations of Schott Bioglass containing considerably less sodium oxide. Schott Bioglass contains even less sodium oxide, so that it must be postulated there a very poor solubility and thus also little interference with the surrounding tissue.

Schepers et al. (1987) were able to prove that bioactive glass is not tissue-inductive (in this instance, not osteoinductive). If, due to the formation of boundary layers, no contact materializes, there is neither a formation of tissue comparable to that of the environment. In case of formation of the boundary layer, the action of this boundary layer is positive as a function of time. With an increasing duration of test, the protective function of this boundary layer became ever more evident, as could be shown in tests with beagles over 4 and 16 months (Schepers et al., 1989).

As Thieme et al. (1982) have already measured by means of X-ray emission (PIXE), an ion-exchange reaction occurs in the aqueous environment on the surface of alkali-containing bioglasses and bioglass-ceramic articles, which proceeds in two phases as claimed by Hench (1974). Phase 1 is dominated by the alkali loss in exchange for hydrogen ions; calcium also diffuses from the material. In phase 2 occurs the hydrolytic cleavage of the Si-O-Si bond with subsequent disintegration of the material. The exchange reactions proceed over about 2 weeks. Later on is formed a predominantly calcium-containing surface film preventing further leaching of the material. The following figure 3 shows results of measurements taken on bone implants.

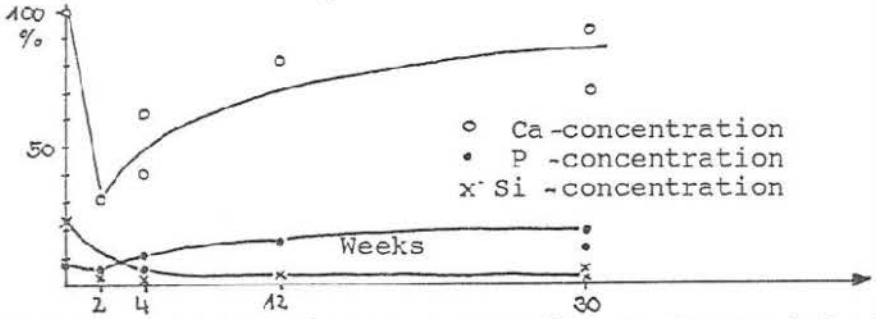


Fig. 3: Element concentration as a function of the period of rest of the Ap 40 biovitroceramic material (Ca concentration of the non-implanted ceramic material = 100 %).

Whereas the silicon curve shown should run, in case of bioinert material, in a way comparable to that of Schott Bioglass, the nearest calcium curve runs in a comparable way, it is true, however not with such a drop during the first two weeks.

In a comprehensive study on male Sprague-Dawley rats (weight: 300 to 350 g; 112 animals altogether), glass-ceramic materials of varying solubility (reduction of the sodium oxide content - poorer solubility) were tested as implants over 245 days. Intermediate tests were conducted on the days 29/30, 60 and 119 "post implantationem". In addition to the local effects, the organs: lungs, liver, kidneys and spleen were examined histopathologically with regard to possible effects. It turned out that the compatibility of the material was good, with the reduction degree of the alkali oxides correlating negatively to solubility. As compared to the control animals which were submitted to the same treatment, however without implantation of the implant, no changes due to test specimens could be identified in animals with an implant, neither tumorigenic effects. Only the regional lymph nodes were somewhat enlarged; they showed an increased number of histiocytes as well as expanded B and T cell zones as a sign of a slightly increased unspecific immunoreaction. Here too, the materials with a reduced alkali-oxide content reacted more faintly than the other ones (Gross and Strunz, 1980).

The bioinert property of bioglass material could also be demonstrated on German shepherd dogs. Artificial hips, coated with bioglass, were implanted for 3 to 17 months. Apart from a negligible effect of irritation with its characteristic infiltrations of macrophages and lymphocytes, the histopathological examination of various organs (not detailed) yielded no indications of changes due to test specimens (Ducheyne et al., 1984).

Also tested was the biocompatibility of glass-cladded identification systems (transponders) on 69 horses (48 mares and 21 foals). To this effect, a transponder was implanted in the left lateral cervical muscles of each animal. The object of this test was, in addition to technical inspections, the migration and pathological findings of the surrounding tissue (histopathological examination). One transponder was implanted in a broken state. 24 hours "post implantationem", the adult animals showed anatomically and pathologically very insignificant effects of irritation in the points of implantation, which were detectable no more during the examination 3 days p.i. The subsequent examinations, performed on the days 28, 81, 110, 158, 193 and 259 p.i., neither yielded any indications of anatomic and pathological changes of the surrounding tissue. The animals showed a good condition, and the reproductiveness - a very delicate parameter for horses - showed standard values. The foals were examined 90 days (10 animals) and 180 days (11 animals) "post implantationem" in the same manner, and the findings were comparable with those of the adult animals. On day 90 p.i., 7 foals and one mare (and, furthermore, the mare in which had been implanted a broken transponder) were put to sleep, and implant as well as surrounding tissue were removed. The tissue samples were fixed in formalin and, in addition, embedded in methyl methacrylate (4 with transponder material and 4 without transponder material); cuts of a thickness of 200 micrometers were

made with the aid of a diamond cutter, dyed and inspected with a light microscope. The consistent findings revealed very little fibrosis as an anticipated tissue reaction to the foreign body without any clinical relevance. The mare, in which the broken transponder had been implanted, showed medium-grade chronic granulomatosis to pyogranulomatosis as a consistent reaction of the subcutis and of the muscular tissue. The unbroken transponder core (chip) was covered by a thin, fibrogenic tissue of low-grade granulomatosis. The surrounding tissue was pathologically inconspicuous. The examinations with regard to migration yielded no indications of significant tissue migrations of the implants in adult as well as young horses (Gabel et al., 1987).

Marking by means of cladded transponders has made a remarkable progress in the Federal Republic of Germany. Glass-cladded transponders for animal identification have thus been used by the Rhineland Horse Studbook, the Oldenburg Breeding Association and the Association of Hanoverian-Warm-Blood Breeders since 1987 and by the Bavarian Haflinger Breeders since 1988.

These systems could likewise be used in pigs. In the Netherlands are available empirical values from more than 300 pigs, where no adverse effects could be observed so far. In the case of pigs, it appeared that the ear base is a suitable point of implantation. In 17 animals (age: 4 weeks), in which the transponders had been implanted in the skin of the ear conch (peripheral position), 7 were missing, and 8 were broken after slaughter, whereas the transponders in 19 animals, implanted at the ear base (central position), were found again unchanged in the original place, after the fattening period, at the time of slaughtering (Merks, 1988).

Re: 2)

Toxicity of main constituents.

Silicon oxide.

As Kitsugi et al. (1989) were able to show on rabbits, silicon oxide proved to be bioinert, as claimed already in 1982 by Hensch and Ethridge. In addition to two glass-ceramic parts, a silicon--oxide glass (99.99 wt %) was implanted in the metaphysis of the tibia of 10 adult male rabbits (weight: 3 to 3.5 kg). One half each of these animals were put to sleep 10 and 25 weeks "post implantationem". Segments containing the implant were removed and dissected (preserved), and the junction point was checked for separation or non-separation from the bone tissue by means of SEM - EPMA (scanning electron microanalyzer - energy dispersive X-ray microanalyzer.

In a second experiment were to be observed early changes. With identical test conditions and methods, 4 rabbits each were put to sleep 2, 5, 10 and 20 days "post implantationem" and examined accordingly. The result showed no significant exchange rate or formation of a layer between bones and the implant. The silicon content decreased rapidly in the surrounding tissue, as could be shown already by Thieme et al. (1982) (see fig. 3).

Potassium, calcium, magnesium and sodium oxides.

The aforementioned oxides occur physiologically in the body of animals. They are constituent parts of the supporting tissue or Co factors in the cell, enzyme or nerve functions as well as many other biochemical reactions in the organism. As components of the implant, they are released to the surrounding tissue as a function of the solubility of the material. The major part, however, serves the formation of the contact layer (interface), i.e. biological apatite crystals are formed. As mentioned already, the boundary layer that has formed substantially prevents further diffusion of the components. It is, in particular, the relatively high content of aluminum oxide and iron oxide that makes Schott Bioglass inert, i.e. the release of components should be distinctly reduced (see further below). On top of that, it has to be anticipated, within the scope of the homeostasis of the electrolytic balance, the physiologically conditioned elimination from the animal body. Only with positively increased electrolytic contents, it must be expected, after a persistent disorder of the homeostasis, toxic and/or pathological results, which are not to be anticipated, however, all the more so as the mass of the implant in relation to the mass of the animal body is negligibly small.

Aluminum oxide

This compound is present mainly as alpha aluminum oxide (corundum). It is insoluble in water and very slightly soluble in acids. The acute toxicity of soluble aluminum compounds is low (e.g. aluminum chloride rat oral LD/50 420 mg/Kg Kgw. related to aluminum). In case of long-term absorption, disorders of the calcium and phosphate balance of animals and humans (calcium is displaced, and phosphate is insolubly complexed) as well as encephalopathies are possible (Forth et al., 1987). However, as reported already by Deutscher et al. (1978), aluminum oxide (as high-purity ceramics) shows a good tissue compatibility, which is a result of the insolubility of the material as against the interstitial body fluid and the very low abrasion of articulating surfaces.

Iron oxide.

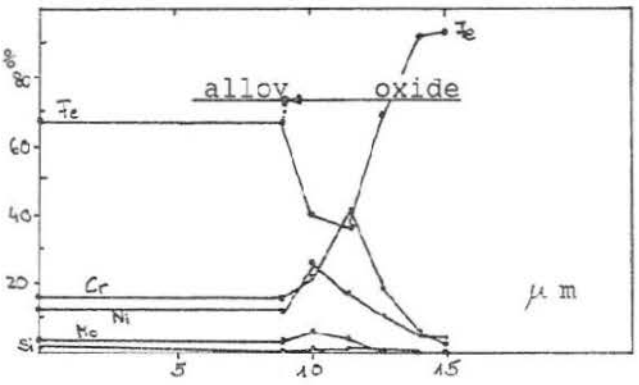
Iron oxide occurs both as iron (II) oxide and iron (III) oxide in the organism. The non-recurring intraperitoneal injection, i.e. the compound can show a systemically toxic effect substantially faster and more distinctly, as barriers such as the gastrointestinal tract or the skin are by-passed, of 20(?) mg iron oxide/kg Kgw. in rats resulted in a weak foreign-body reaction which was no more detectable 150 days "post applicationem" (Engelbrecht and Burger, 1986).

Long-time studies are not available. It is, however, pointed out that iron (III) in complex compounds with, for instance, saccharose, hydroxide dextrine or sorbitol citrate, is, in case of iron deficiency anemia, injected in humans intramuscularly or intravenously. The sporadically occurring soft-parts tumors after iron (III) complex therapies could not be shown as a causal connection (IARC), 1973.

Piglets, showing, as a matter of principle, an iron deficiency anemia "post partum", are treated in the same manner without any visible toxic effect (Sommer et al., 1978).

As Gheyen et al. (1983) were able to describe (see fig. 4), iron changes over in parts from a metal alloy, in case of bioglass cladding, to the glass compartment, just like silicon penetrates the alloy. A steady state is quickly attained, which is of eminent importance for the lifetime of the actual implant, on one hand, and of the cladding, on the other. The addition of iron oxide thus further increases the bioinert behaviour of the cladding and thereby inhibits to a major extent its own diffusion into the surrounding tissue. The diffusion of silicon into the metal is negligible.

Fig. 4



Boron oxide

Boron oxide shows a very low acute toxicity after subcutaneous application in mice (LD/50 1740 mg/kg Kgw.) and guinea pigs (LD/50 1200 mg/kg Kgw.). The daily oral absorption of a slurry containing 10 % boron oxide in water via throat sound over 3 weeks was tolerated by growing rats without any symptom of an impairment (ACGIH, 1988).

Nevertheless, a higher content of boron oxide increases the solubility of the cladding material, which results in a reduction of the lifetime and thus of the operativeness of the implant. Moreover, there was an undesirable introduction of the components into the surrounding tissue, which, in sufficient quantity, might lastingly affect the homeostasis in the organism of animals (Gross and Strunz, 1985).

Due to its germ-reducing effect, boron has been used therapeutically as a disinfectant in human medicine (example: Soor). A significant, direct, systemically toxic effect is hardly probable.

Schott Bioglass shows a distinctly lower content of boron oxide than Schott glass 8350 (see Annex 1 and 2), which has been admitted already as an encapsulating material in the United States (Schott, 1990).

Barium oxide

With the exception of barium sulphate, which is sufficiently insoluble, and which is used as a contrast medium for gastrointestinal radiography, the other barium compounds such as barium oxide, barium peroxide, barium hydroxide, barium chromate, barium carbonate and barium nitrate turn out to be definitely toxic. The toxicodynamic effect has been analyzed well. Main target organ is the muscular system, mainly the cardiac muscle, the stimulation of which is increased. However, the skeletal, arterial, intestinal and bronchial muscular functions are also affected. Additional effects occur on the hemapoetic system as well as on the cerebral cortex (Sollmann, 1948).

Fazeka et al. (1953) showed that the non-recurring subcutaneous application of an aqueous solution of barium chloride in a dose of 5 mg/kg Kgw. in rabbits led to death within 2-2.5 hours. Chronic symptoms of poisoning arose after application of 2.5 and/or 10 mg/kg on rabbits. During autopsies after 98 and 193 days, results were collected on the central nervous system. It is surely remarkable that the barium compounds diffuse relatively quickly, as a function of their solubility, from the point of application into the organism, as could be proved on rats by Thomas et al. (1973).

Comparing again the analyses listed in the Annex, the barium oxide content was lowered from 2.7 % (Schott glass 8350) to 1.0 % (Schott Bioglass), which leads to a considerable reduction of a potential intoxication. Here again, it is pointed out the minimized solubility of the encapsulating material and of the substantial inhibition of barium in the organism, which is connected therewith.

Recapitulation and evaluation

The objective of the expertise is to assess the tissue compatibility of Schott Bioglass on the basis of test results with similar bioglasses and/or bioglass-ceramics as implants in the organism of animals, with the inclusion of toxicological aspects of the single components. The corresponding requirements on the encapsulating material are defined as follows:

- as an implant altogether not to cause, after adaptation, any foreign-body reactions (continued inflammation processes) up to yatrogenic reactions (immunologically conditioned repulsive processes);

- extensive prohibition of the diffusion of single components into the organism, in order to

a) guarantee the protection of the actual implant over its period of use, i.e., as a rule, over the lifetime of the implant carrier,

b) preclude functional, systemically toxic as well as locally irritative effects.

The test results of various authors (Ball et al., 1988; Blencke et al., 1975, 1978; Schepers et al., 1987, 1989; Gabel et al., 1987; Ducheyne et al., 1984) clearly show that bioglasses as well as bioglass-ceramics generally exhibit a good tissue compatibility regardless of the time of implantation and of the implantation carrier (animal species). After a necessary phase of adaptation, no anatomico-pathological and/or histopathological results were collected during the tests in the points of implantation of the animals, suggesting significant changes due to test specimens. Yatrogenic reactions neither occurred (Blencke et al., 1975). Histopathological examinations of further organs such as lungs, liver, spleen and kidneys yielded no effects which are considered as being in a causal connection with the implantation material. The homeostasis has in no case been affected, as was made evident by the behaviour and the general condition of the animals. References to neoplastic changes or tumorigenic effects are missing (Gross and Strunz, 1980).

The only effect that was diagnosed in a series of tests - normally during the phase of adaptation already mentioned - was a temporary slight irritation which, in most cases, eased off quickly, and characteristic of which was a low-grade infiltration of macrophages and lymphocytes (Ducheyne et al., 1984; Gross and Strunz, 1980; Gabel et al., 1987). It has not been clarified unequivocally to which extent the actual process of implantation must be held responsible for these effects.

Investigations of implantation surfaces showed, in case of implants with reduced solubility (decrease of sodium-oxide content; addition of aluminum oxide and further metal oxides), a clearly diminished leaching rate of individual components. The as yet diffused components have, for the most part, formed a thin apatite-crystal layer on the surface which has been covered by the surrounding tissue with a fine fringe of connective tissue fibers (Ball et al., 1988; Thieme et al., 1982; Blencke et al., 1975; Gabel et al., 1987; Koehler and Retemeyer, 1978).

The formation of this thin fringe of connective tissue is most obviously jointly responsible for the lacking migration of the soft-parts implants with regard to appropriate implantation locations which are subject only to small processes of movement (Merks, 1988).

Relevant data on the toxicity of silicon oxide for the present form of application (implantation) are not available. Examinations of animals have, however, shown that silicon oxide must be rated as bioinert. The small quantities still diffusing from the implant are converted with calcium oxide into the crystals mentioned already and are also bioinert (Koehler and Retemeyer, 1978; Thieme et al., 1982; Blencke et al., 1975).

Potassium, calcium, magnesium and sodium oxides, which occur physiologically in the organism of animals, display toxic effects only if substantially overdosed, starting with a disturbed homeostasis of the electrolytic balance. The aforementioned results gave no indications, however, of any changed homeostasis.

The acute effect of aluminum oxide is of low toxicity; only after a repeated increased absorption do disturbances of the calcium and phosphate balances occur as well as encephalopathies (Forth et al., 1987), but, due to its insolubility of nearly 100 %, it shows a good tissue compatibility (Deutscher et al., 1978).

Iron (II) as well as iron (III) oxides are toxicologically harmless; they occur physiologically in humans and animals and are used therapeutically (IARC, 1973). Iron oxide contributes just as aluminum oxide to the reduction of the leaching process (Gheysen et al., 1983).

Boron oxide shows a very low acute as well as subacute toxicity (ACGIH, 1986). It increases, however, the solubility of the encapsulating material and thus the diffusion of individual components, which might perhaps provoke a toxic effect (Gross and Strunz, 1985). Schott Bioglass exhibits here a clearly reduced content as compared to Schott glass 8350, which will prove to be positive.

From the toxicological point of view, only barium oxide turns out to be critical, as is shown by the present findings. However, the same applies here as to boron oxide. The content of Schott Bioglass is 1 % as compared to 2.1 % in Schott glass 8350, which distinctly reduces, or makes rather unlikely, a potential toxic effect.

The present facts make Schott Bioglass appear as highly qualified for the encapsulation of implants due to the anticipated good tissue compatibility, stability and negligible probability of a toxic effect.

A separate test does not appear to be necessary, neither from the viewpoint of avoiding animal experiments. It shall be pointed out yet that the application of implants with such claddings has been proposed in 1988 already by the Advisory Veterinary Committee of the European Community (Landwirtsch. Wochenbl. (= Agricultural Weekly), 42; 10.20.1988).

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APPENDIX E: UNDETECTED TAGS IN COMMERCIAL CATCHES

Tagging programmes involve the release of a batch ('cohort') of tagged fish and scanning for these fish in future catches. The food safety risk primarily arises from tags that are present, but not detected in commercial catches.

E.1 Tags in the SNA 1 population

The number of tagged fish from a tagged cohort present in the population decreases over time through natural mortality, and as a result of fishing. For snapper, estimates of the natural mortality rate, M, range from 0.05 to 0.075, with 0.075 the value assumed in the base case SNA 1 assessment conducted in 2013 (Ministry for Primary Industries 2016).

Because snapper are a relatively long-lived fish, fish from a tagged cohort persist in the population for several decades (Figure E-1). Fishing obviously removes fish at an increased rate, causing a more rapid decrease in numbers of the tagged cohort.

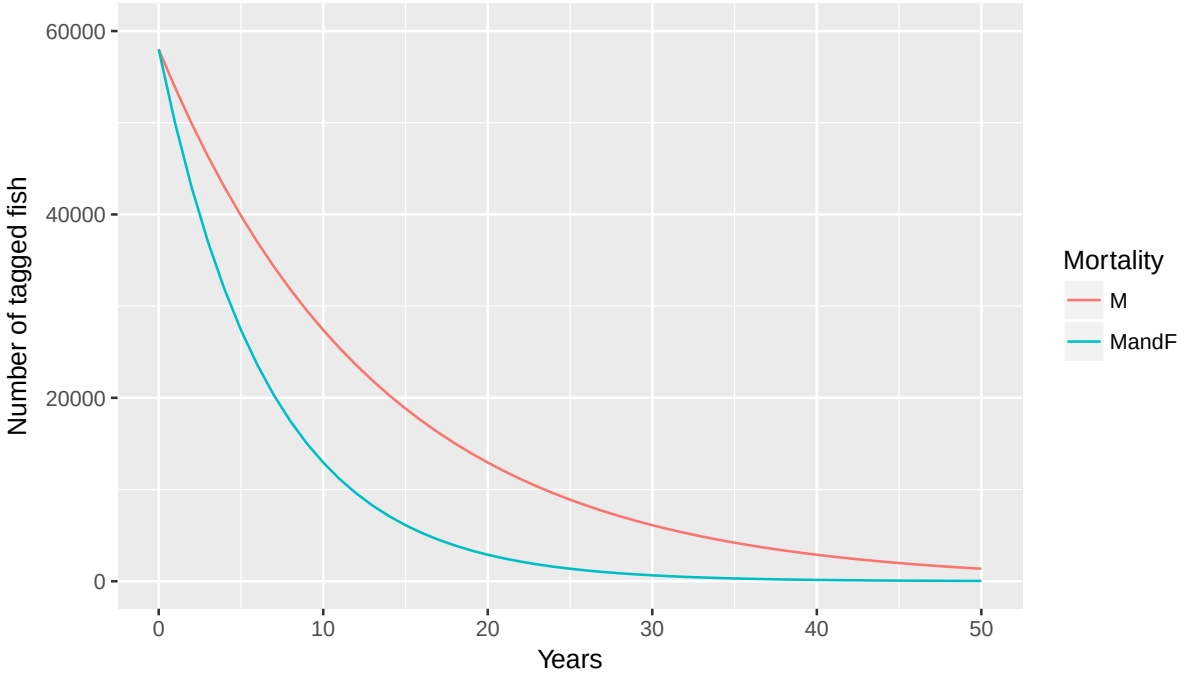

Figure E-1: Change in cohort size over time through natural mortality, and natural and fishing mortality, for $M = F = 0.075$ and $N_0 = 58000$.

E.2 Tags in the SNA 1 commercial catch

A number of designs for an SNA 1 tagging programme were evaluated by McKenzie et al. (2015) from the perspective of achieving sufficiently precise estimates of abundance and movement, while minimising costs. The one-off design that targets the recapture of 1500 tagged fish is used here for the purposes of illustration.

Simulations for the one-off tagging programme indicated that, for a recapture target of 1500 tags, 58 000 tags would need to be released, and 2 915 200 fish scanned. With the Total Allowable Commercial Catch (TACC) of SNA 1 at 4500 t and an average fish weight of approximately 1 kg, this implies scanning 64.8% of the commercial catch.

McKenzie et al.'s simulations assumed 100% detection, but 85% detection was estimated for the previous SNA 8 programme. As a result, 225 of the 1500 tags in the scanned catch could go undetected, and a

further 528 tags would be present in the unscanned catch.

If scanning ceased after the first year, all future catches of tagged fish would be undetected. The change in size of the tagged cohort over time allows approximate numbers of undetected tags to be estimated (Figure E-2).

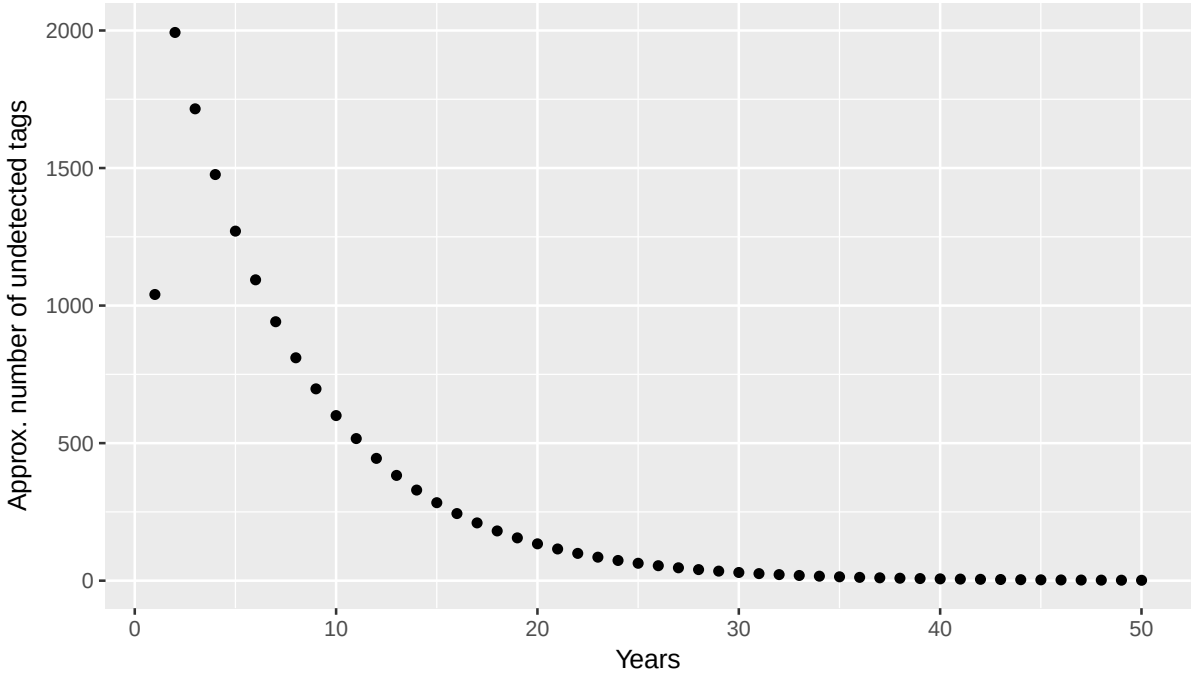

Figure E-2: Approximate number of undetected tags in the commercial catch for a one-off tagging programme.

In the one-off programme design, scanning ceases after the first year. The year with the greatest number of undetected tags is the year after scanning ceases. In that year, approximately one fish in every 2258 (0.044%) in the commercial catch would be expected to have an undetected tag. For the first 10 years after tagging, the average rate of undetected tags is one fish in every 3866 (0.026%).

E.3 Reducing the number of undetected tags

Strategies for reducing the number of undetected tags in the commercial catch could include:

- continuing scanning beyond the first year;
- scanning a greater proportion of the commercial catch;
- improving detection rates.

E.3.1 Ongoing scanning

If scanning is continued for 10 years after tagging (rather than one year), and at the same intensity as required for the one-year design, then the average rate of undetected tags over the 10-year period is one fish in every 7755 (0.013%) (Figure E-3).

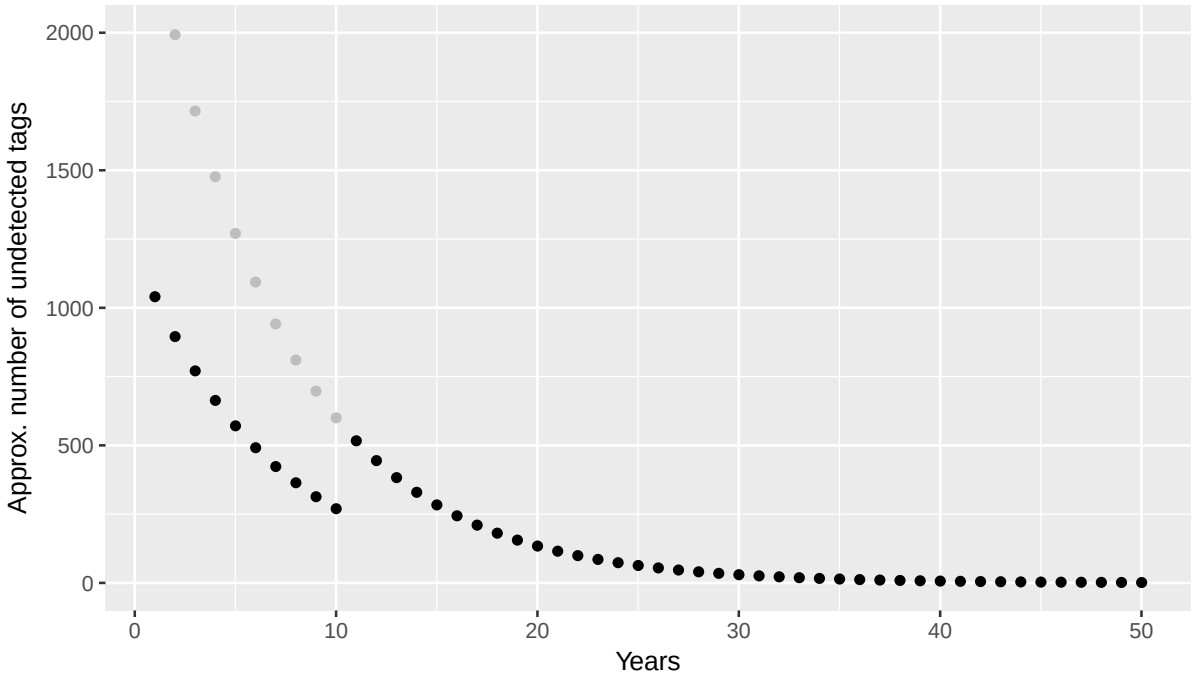

Figure E-3: Approximate number of undetected tags in the commercial catch for a one-off tagging programme with tag scanning occurring for 10 years (black points) rather than one year (grey points).

E.3.2 Scanning more of the catch

The original one-off programme required 64.8% of the commercial catch to be scanned. Alternatively, processers could target scanning all of the commercial catch (for the purposes of illustration, 95% of the commercial catch is assumed to be scanned). Note that while tagging programme designs have focused on at-sea scanning, the scanning of all catch is assumed to require implementation at processing sites.

For the first 10 years after tagging, with 95% of the catch being scanned, the average rate of undetected tags is one fish in every 1.8102×10^4 (0.006%).

E.3.3 Improved scanning

The 85% scanning success rate assumed in the illustrations above was based on estimates from the SNA 8 programme. That programme used specifically designed tags and scanners. Although the basic physics that limits PIT tag detection distances has not changed, preliminary testing (Middleton et al. 2017) indicates that higher detection rates for scanning for tags in bins of fish should be possible with contemporary tags and scanners.

If 95% scanning efficiency is achieved, and 95% of commercial catches are scanned, then for the first 10 years after tagging the average rate of undetected tags is one fish in every 3.574×10^4 (0.003%).

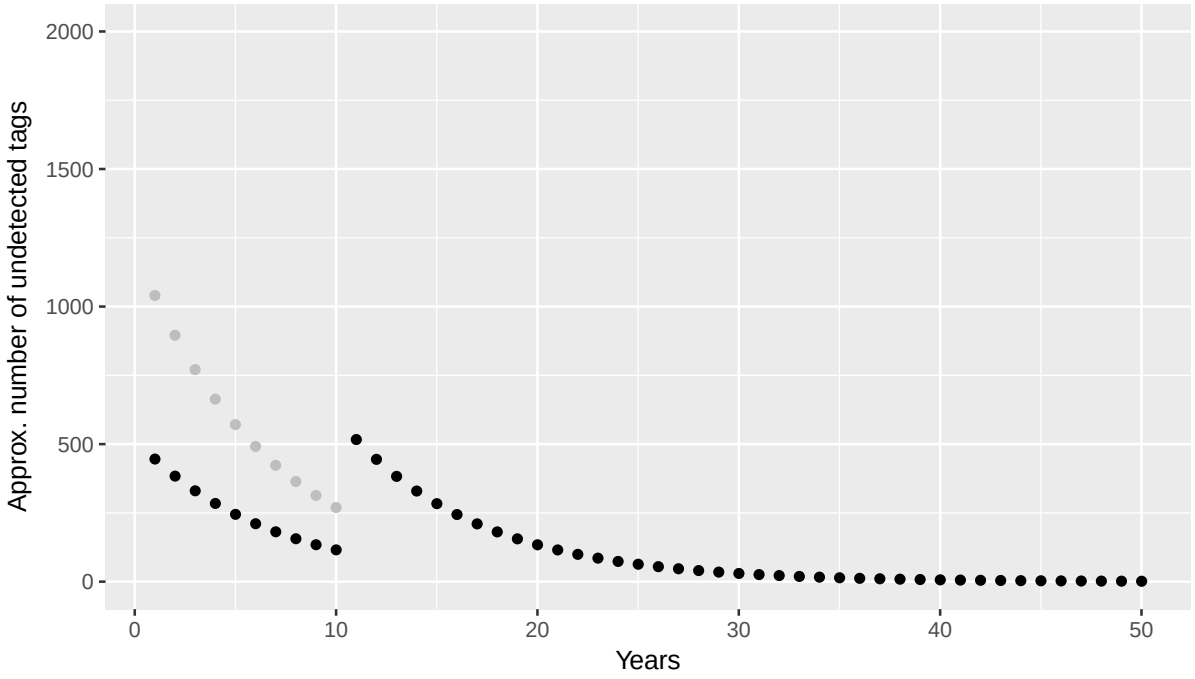

Figure E-4: The impact of scanning 95% of the commercial catch (black points) relative to the 65% required in the one-off design (grey points).

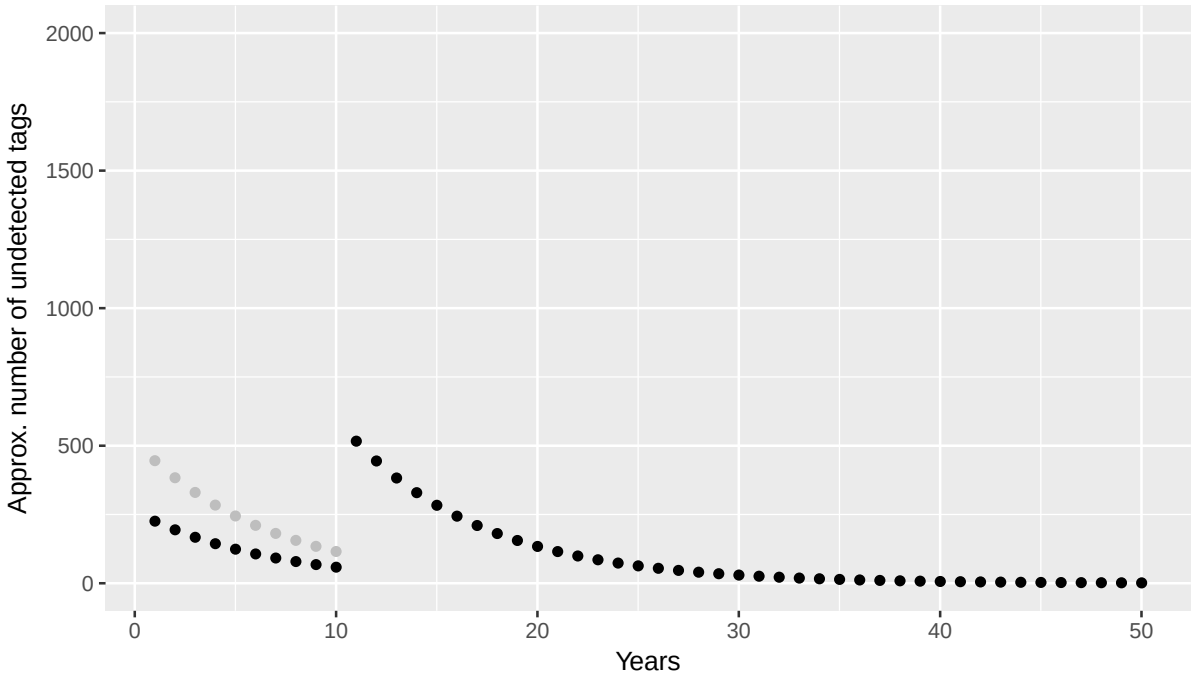

Figure E-5: The impact of increasing tag detection rates to 95% of the commercial catch (black points) relative to the 85% assumed previously (grey points), with 95% of the catch scanned.