Part 4 Assessment of the potential impacts of the proposed action on additional listed migratory species identified in an ERT search on 13 July 2017

The following migratory species although listed prior to 20 June 2016 (when the original ERT search was conducted) appeared in the ERT search for the first time on 13 July 2017 because their distributions were updated in SPRAT in March 2017.

- Curlew Sandpiper *(Calidris ferruginea)*
- Common Sandpiper (*Actitis hypoleucos*)
- Sharp-tailed Sandpiper (*Calidris acuminata)*
- Red Knot (*Calidris canutus*)
- Pectoral Sandpiper *(Calidris melanotos)*
- Sei Whale (*Balaenoptera borealis*)
- Fin Whale (*Balaenoptera physalus)*
- Common Noddy *(Anous stolidus)*
- Lesser Frigate Bird *(Fregata ariel)*
- Greater Frigate Bird *(Fregata minor)*

These species were identified in the SPRAT search of 13 July 2017 because their distributions were updated in SPRAT subsequent to the controlled action decision for this project. The Department recently assessed the potential impacts of the proposed action on the above species and concluded that it was highly unlikely that they would be significantly impacted by the proposal.

The following is a summary of this assessment.

Curlew Sandpiper (*Calidris ferruginea*)
The Curlew Sandpiper is distributed around most of the Australian coastline (including Tasmania). It occurs along the entire coast of NSW, particularly in the Hunter Estuary, and sometimes in freshwater wetlands in the Murray-Darling Basin. The Curlew Sandpiper breeds in Siberia and migrates to Australia for the non-breeding period, arriving in Australia between August and November, and departing between March and mid-April.

Individuals of this species recorded on LHI are from populations that occur throughout coastal Australia. The Department concluded that it is unlikely that the proposed action will have a significant impact on the Curlew Sandpiper because it is a rare/accidental visitor to LHI (recorded on 10 occasions since 1902).

Common Sandpiper (*Actitis hypoleucos*)
According to SPRAT, the total population of the Common Sandpiper is in the order of 2 455 000–4 030 000 individuals. The East Asian-Australasian Flyway population is estimated to be 190 000, whilst individuals within Australia during the non-breeding period are estimated to be approximately 3000.

The Common Sandpiper breeds in Eurasia and moves south for the boreal winter, with most of the western breeding populations wintering in Africa, and eastern breeding populations wintering in south Asia to Melanesia and Australia.

There are no records of this species in *Australian Field Ornithology, Volume 21 Supplement 2004* which is a detailed review of LHI bird records. The Department concluded that it is unlikely that the proposed action will have a significant impact on the Curlew Sandpiper because it is an accidental visitor to LHI.

<u>Sharp-tailed Sandpiper (*Calidris acuminata*)</u>
According to *Australian Field Ornithology, Volume 21 Supplement 2004* the Sharp-tailed Sandpiper is a rare regular visitor to LHI. LHI is not one of the 39 important international sites identified in SPRAT for this species. The Department concluded that it is unlikely that the proposed action will have a significant impact on this species because it is a rare visitor to LHI in small numbers.

<u>Pectoral Sandpiper (*Calidris melanotos*)</u>
This species has been recorded on LHI on four occasions over a 28 year period (five birds in total). The Department concluded that it is unlikely that the proposed action will have a significant impact on this species because it is a rare visitor to LHI in small numbers.

<u>Sei Whale (*Balaenoptera borealis*)</u>
According to SPRAT, Sei whales have been infrequently recorded in Australian waters. This species is unlikely to be present, or present in small numbers, in the vicinity of the LHIG.

At sexual maturity, Sei whales can reach lengths of 17.7 m in males and 21 m in females. Sei whales feed on planktonic crustacea, in particular copepods and amphipods.

The Department concluded that there is no credible pathway by which this species could have sufficient exposure to sufficient bait to result in illness or death to any individuals. Sei whales are therefore unlikely to be significantly impacted by the proposed action.

<u>Fin Whale (*Balaenoptera physalus*)</u>
The Fin whale is the second-largest whale species, after the blue whale (*Balaenoptera musculus*). Adult whales range between 20 and 27 m long and weigh more than 70 tonnes.

Fin whales feed intensively in high latitudes and may also feed to some extent, depending upon prey availability and locality, in lower latitudes. Fin whales feed on planktonic crustacea, some fish and cephalopods (crustaceans). This species is unlikely to be present or present in small numbers in the vicinity of the LHIG.

The Department concluded that there is no credible pathway by which this species could have sufficient exposure to sufficient bait to result in illness or death to any individuals. Fin whales are therefore unlikely to be significantly impacted by the proposed action.

<u>Common Noddy (*Anous stolidus*)</u>

This species breeds in the LHIG. In 1996, the total Australian population of the Common Noddy was estimated to be between 174 480 and 214 130 breeding pairs. A 2012 IUCN assessment of the species' conservation status noted that the global population size was estimated between 180 000 and 1.1 million individuals; no estimated proportion of the population residing in Australia is available and according to *Australian Field Ornithology, Volume 21 Supplement 2004* in the early 1970s there were approximately 1000 breeding pairs on LHI. It is likely it has become more abundant since cats were eliminated on LHI.

This species is unlikely to be impacted by the proposed rodent eradication project because it is present on LHI between September and May outside the proposed baiting period.

Lesser Frigate Bird *(Fregata ariel)*

The Lesser Frigate Bird is a vagrant to LHI. There have been a number of unconfirmed sightings and one positive record since 1887. The Australian population is estimated to be between 18 862 and 19 631 breeding pairs.

This species is unlikely to be impacted by the proposed rodent eradication project because it has only been positively recorded on one occasion in the vicinity of LHI.

Greater Frigate Bird *(Fregata minor)*

According to SPRAT, the total Australian population of this species is estimated to be approximately 1600 breeding pairs. The only record of a Greater Frigate bird in the vicinity of LHI, that the Department has been able to locate, was a sighting over Roach Island in March 2007 referred to in a Friends of LHI newsletter (Issue 20 Autumn 2007).

This species is unlikely to be impacted by the proposed rodent eradication project because it has only been recorded on one occasion in the vicinity of LHI.

Appendix 3

Summary of LHIB response to the Phalen review of the captive management program

In June 2017, the Department engaged the professional services of Associate Professor David Phalen from the University of Sydney to review Taronga Zoo's Captive Management Plan.

Professor Phalen's qualifications are Doctor of Veterinary Medicine (DVM; PhD, Diplomat of the American Board of Veterinary Practitioners (Avian Specialty). His research interests include:

- Infectious diseases of pet birds and wildlife including viruses, bacteria, fungi, and parasites.
- Health and welfare of exotic pets, zoo animals, and wildlife.
- Medicine and surgery of wildlife, zoo animals and exotic pets.

The questions to be addressed in the review were:

- Is the proposed captive management program consistent with the best captive management/avian husbandry practice, including operating procedures and protocols and proposed responses to disease outbreaks?
- Does the program adequately address potential events that could be reasonably expected to adversely impact the captive populations of Woodhens and Currawongs such as avian disease or viruses, contaminated food, fire and meteorological events such as a cyclone?
- Are the proposed staffing arrangements adequate in terms of staffing levels and the qualifications and experience that are required?
- Noting risks that are likely to occur and reasonably foreseeable, do you agree that a second captive management population is not necessary?
- If you are not satisfied that the risks have been adequately mitigated in regard to any of the above questions, what do you recommend in order to minimise potential impacts on the Woodhen and Currawong populations?

The review recommendations and responses are below:

- **Woodhens and Currawongs should not be housed offshore because the opportunities for insect borne infectious (particularly parasitic) diseases are too high and animals from offshore facilities could not safely be returned to LHI.**
  The Department and LHIB agree with this recommendation. Birds will not be housed on the mainland.

- **Hospital facilities and the kitchen should be in separate buildings.**
  LHIB investigated alternatives without success. The bird pens are on LHIB owned and controlled land. The hospital facilities and kitchen are on a site leased to a commercial operator who runs a plant nursery. He agreed to the building being used for captive management purposes. The hospital facilities and kitchen are currently separate rooms within the same building structure. The kitchen is in an open, under cover space and the veterinary room is enclosed with a lockable door. Currently, to access the veterinary room, staff have to walk through the food preparation area. The LHIB have agreed to comply with the recommendation that separate entry points be constructed and a solid wall be built between the two areas.

- **Straw from the mainland should not be used as a substrate (associated with aspergillosis in other bird species). Clarification required re how often and how much of the substrate in the woodhen enclosures will be changed.**
  The revised Captive Management Plan states that LHIB have committed to providing and storing mulch in secure, dry, rodent-proof skip bins to avoid contamination in the months leading up to the project. Recommended volumes will be provided to LHIB by Taronga staff

to allow for appropriate planning and storage. Mulch will be provided weekly by LHIB (dried cut palm fronds/wood chip mulch) and additional substrate will be sourced from the mainland. Any imports must comply with any LHIB bio-security regulations. If an alternative substrate is introduced, it will be trialled in one pen first to ensure there are no problems before using it in other pens. Substrate changes are scheduled once per week for each pen, with approximately 50-100mm new material on the top layer and will be monitored by staff daily. Taronga Zoo indicated that straw substrate was intended as an emergency backup substrate if suitable litter could not be sourced on the island.

- **If woodhens are fed on trays and provided water in shallow bowls, faecal contamination of the food and water could occur. Poultry feeders with multiple openings, as used for growing chickens, and poultry waterers should be considered.** The revised Captive Management Plan states that a variety of food delivery methods will be used to allow staff to employ options that are best suited to the type of food being fed and to provide enrichment to birds. All feeding options will be conscious of oral faecal exchange and will be changed daily. In the 2013 trials, stainless steel bowls were placed in tubs to prevent birds standing in them and tipping food. This was found to be successful in reducing contamination. Feeder trays will also be available.

- **Biosecurity protocols should be reviewed to make sure that feral or semi-domestic chickens cannot gain access to the site.** LHIB indicated that 80% of domestic fowls will be eaten/destroyed prior to baiting commencing. 20% will be penned for the duration of the eradication program on owner's lots, no free ranging will be permitted. There aren't any wild (domestic) fowls on LHI.

- **Appropriate antibiotics and pain medications, as well as, the necessary supplies for supportive care need to be on LHI so that treatment can begin immediately**. Antibiotics and pain medication supplies will be on LHI in a fully stocked pharmacy from the outset, along with a veterinary nurse. Additional pharmacy items can be flown out if necessary. A qualified veterinarian will be present at the facility when birds arrive and are released as required.

- **The plan to transfer preselected birds to another site on LHI if an infectious disease outbreak occurs should be a last resort. Additional biosecurity protocols should be established that include both keeping the birds *in situ* and minimising the chance of the movement of disease between enclosures.** LHIB have undertaken to implement these recommendations.

- **The daily amount of food being fed to each bird represents approximately 50% of the bird's weight. Track bird weights and vary the amount of food being provided accordingly to avoid obesity**. The revised Captive Management Plan states that each bird will be fed 35 grams of food which is less than 8% of the weight of an average Woodhen. A subset of birds from each pen will be weighed on a rotating roster and will be tracked. Food provided will be adjusted as necessary. Initial amounts fed during the trial period were greater in order to ensure that all individuals were getting access to food while Taronga staff determined whether group housing would alleviate territorial aggression. Accurate diet, health and weight records will be maintained for each bird.

- **Currawongs should be fed cooked eggs, not raw eggs.** The currawongs will be fed cooked eggs.
- **If natural plants/foliage are used in pens increased ventilation should be used to remove moisture. *Aspergillus*: adequate ventilation is required to prevent moisture**

build up and mould growth in the enclosures. Open the aviaries as much as possible to take advantage of natural ventilation and consider using fans.
The revised Captive Management Plan indicates that the site has been designed to allow for greater airflow following adjustments based on findings from the 2013 trial. As per the recommendation, Ventilation will be monitored carefully. The smoke test and a variety of approaches will be employed to improve ventilation (opening the side walls on the domes, incorporating shade cloth into the roof panels, installation and portable fans).

- **Outline a decision making process as to how veterinary staff will respond to the detection of an infectious disease in an apparently healthy bird or birds.**
  This is outlined in a new diagram - attachment 15 to the revised Captive Management Plan.

- **A second captive management facility on LHI is not essential and would significantly increase the cost as all the support structures would need to be duplicated.**
  A second captive management facility will not be built on LHI.

- **Supplementary heat will be needed in hospital pens when very sick or badly injured birds are present.**
  LHIB indicated that additional pens are available to separate groups or families of woodhens if needed. These are similar to the holding pens and do not have supplementary heating. Hospital cages with provision for heat lamps will be available to house single sick birds for intensive treatment. Portable heat lamps can be placed in the pens or aviaries if required.

- **Dead birds should not be taken off LHI for post-mortem examination, they will be less than suitable diagnostically. One or more of the staff should be trained to do a post-mortem examination collecting specimens for testing as well as formalin fixed tissues for histopathology.**

  Husbandry staff on the Island will be trained in the conduct of necropsies and the collection of suitable samples for testing when a veterinarian is not present. The veterinary nurse will undertake necropsy examinations. At least one other senior bird keeper who is trained in taking necropsy samples will also be present.

- **Additional details are required regarding which enteric pathogens will be tested for when birds are delivered to the captive management facility.**
  The revised Captive Management Plan indicates that the following enteric pathogens will be included in the faecal screening panel: *Salmonella, Campylobacter, Yersinnia,* Shigella and Vibrio. Additional faecal cultures may be undertaken if required (indications could include a bird becoming unwell or healthy carrier bird(s) being identified on arrival. Carrier birds will be monitored.

- **Other matters**
  The reviewer suggested using a washing machine to wash dishes and utensils. Taronga indicated that they are satisfied that dishes can be thoroughly washed using detergent and water in a sink, then rinsed and disinfected using F10 Super Concentrate (F10SC) disinfectant (if infectious organisms are identified in healthy birds or if a bird is unwell).
  The temporary housing facility will be used if a catastrophic weather event occurs. Two separate domes and the design of the pens within them will separate the woodhens into two groups that can be isolated by strict husbandry and infection control measures. Within each dome the pens are designed so that each can be isolated in terms of equipment, access and transfer of material to minimise cross contamination between pens.

FOI 190702
Document 2d

Report on the Human Health Risk Assessment for the Lord Howe Island's proposed Rodent Eradication Program

NSW Chief Scientist & Engineer

July 2017

The Hon. Gabrielle Upton MP
Minister for the Environment
Minister for Local Government
Minister for Heritage
52 Martin Place
SYDNEY NSW 2000

Dear Minister,

Report – Independent Human Health Risk Assessment for the Lord Howe Island's proposed Rodent Eradication Program

In June 2016, your predecessor wrote requesting that I assist the Lord Howe Island Board in undertaking an independent Human Health Risk Assessment for the Lord Howe Island's proposed Rodent Eradication Program in line with the Terms of Reference (see Appendix 1). As planned, an Expert Panel was convened and a suitable firm procured (Ramboll Environ Pty. Ltd.) to undertake the Human Health Risk Assessment, with input and review of the Expert Panel.

The purpose of this report is to provide you with an overview of the process, the finding of the Human Health Risk Assessment and some observations and recommendations. The report of Ramboll's is included as Appendix 2 of this report.

I understand that the Human Health Risk Assessment is important for the Lord Howe Island community. During discussion between the Lord Howe Island Board (the Board) and my office, the Board has expressed an interest in representatives from the Expert Panel and the Office of the Chief Scientist & Engineer attending the island to participate in a community engagement event, discussing the outcomes of the Human health Risk Assessment. I would support this suggestion and my office would be willing to assist should this occur.

I would like to acknowledge the Expert Panel members, Dr Chris Armstrong, Professor Brian Priestly and Emeritus Professor Stephen Leeder, and thank the Lord Howe Island community for their assistance and input into this project.

Yours sincerely,

Mary O'Kane
Chief Scientist & Engineer
19 July 2017

EXECUTIVE SUMMARY

At the request of the Minister for the Environment, the NSW Chief Scientist & Engineer commissioned an independent Human Health Risk Assessment for the Lord Howe Island's proposed Rodent Eradication Program. The Rodent Eradication Program proposes to use the rodenticide brodifacoum, across the island to eradicate both rats and mice. The rodenticide, in the form of Pestoff 20R, would be distributed by aerial baiting, hand distributed, and in bait stations and trays.

Ramboll Environ Pty. Ltd. was engaged to undertake the Human Health Risk Assessment. An Expert Panel was convened to oversee its development and to review the Human Health Risk Assessment.

The Human Health Risk Assessment looked at a number of potential exposure pathways of the rodenticide to humans, including exposure through soil, air (dust), sediment, surface water, tank water as well as food sources such as seafood and locally grown fruits and vegetables. Potential risks from these pathways were then considered for those most sensitive, which included toddlers, school children, pregnant women and adults spending large amounts of time outside.

A quantitative risk assessment of these exposure pathways and population groups concluded that exposure to brodifacoum from all potential sources are below those likely to result in adverse health effects.

The Human Health Risk Assessment also assessed potential exposure due to ingestion of pellets and found that ingestion of one or a few pellets by a child is unlikely to result in observable anticoagulant effects.

While exposure to the rodenticide via the Rodent Eradication Program was not likely to result in adverse health effects, the pathways contributing most to projected exposure included:

- ingestion of soil
- ingestion of tank water
- dermal contact with soil
- inhalation of airborne dust during aerial operations.

The Human Health Risk Assessment report (the Report) was reviewed by the Expert Panel. The Expert Panel supported the conclusions of the Report noting that while adverse health effects are not expected, identification of the major pathways can allow those concerned with exposure to implementation mitigation strategies.

The Expert Panel noted that community concerns are greater than the scope of the Human Health Risk Assessment. These concerns include issues around health and wellbeing (e.g. anxiety and stress) and the implementation of the Rodent Eradication Program, such as the likelihood of success and possible need to undertake further eradications at a later date. It is clear that the Rodent Eradication Program is a divisive issue for the island, which has potential to affect social cohesion. Enhancement of community consultation and engagement may assist with alleviating some of these concerns, although expert advice or assistance from professionals should be considered to assist with health and wellbeing related concerns.

Planning for the case of the rats re-emerging will be considered through the Lord Howe Island Board's rodent detection monitoring program. In such a case, measurement and monitoring should enable early intervention, and consideration of other possible approaches. Further, resistance to brodifacoum has been considered and if necessary additional strategies will be implemented to address this issue. Finally, should the Rodent Eradication Program need to be repeated at a later date, new technologies that are currently being researched (including reproductive technologies) may be considered noting that further research and commercialisation is required before being available commercially.

It is understood that other relevant approvals processes will look at environmental outcomes (effect of brodifacoum on non-rodent species), likelihood of success of the eradication, and approval of helicopter operations during the Rodent Eradication Program (Civil Aviation Safety Authority). The results of these approvals and the recommendations of this report will be considered by the Lord Howe Island Board.

1 RECOMMENDATIONS

Recommendation 1
That the Lord Howe Island Board note the Human Health Risk Assessment report and its advice that the proposed Rodent Eradication Program is not expected to result in adverse health effects for any individual due to exposure to brodifacoum.

Recommendation 2
Noting the considerable remaining community concern on Lord Howe Island, that the Minister request the Lord Howe Island Board to deliver:

1. a communication strategy for the period before and during the Rodent Eradication Program that clearly articulates the following:
    - the reason for the eradication and approach chosen
    - guidance to residents and visitors on actions that they should and could take during the Rodent Eradication Program to minimise exposure to brodifacoum
    - plans for follow-up measures that will be taken after the eradication program
2. a monitoring strategy to measure the outcomes and impacts of the Rodent Eradication Program, including for re-emergence of rodents, as well as triggers that would lead to further action
3. reports to the Minister following the Rodent Eradication Program on community and environmental outcomes, at designated timeframes, such as one month after the second bait distribution, one month after re-introduction of birds and cattle, and two years post the Rodent Eradication Program.

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2 INTRODUCTION

In June 2016, the Hon. Mark Speakman SC MP, Minister for the Environment, requested the NSW Chief Scientist & Engineer (CSE), Professor Mary O'Kane, assist the Lord Howe Island Board (LHIB) in undertaking an independent Human Health Risk Assessment (HHRA) for the Lord Howe Island's (LHI) proposed Rodent Eradication Program (REP). The CSE was requested to:

- provide advice on commissioning the HHRA
- convene an Expert Panel to oversee the HHRA
- provide advice to the Minister for the Environment on the HHRA.

An Expert Panel was convened, consisting of:

- Professor Mary O'Kane, NSW Chief Scientist & Engineer (Chair)
- Dr Chris Armstrong, Director, Office of the Chief Scientist & Engineer (Deputy Chair)
- Professor Brian Priestly, Director of the Australian Centre for Human Health Risk Assessment, Monash University School of Public Health & Preventive Medicine (Independent Expert)
- Emeritus Professor Stephen Leeder, Public Health and Community Medicine, University of Sydney (Independent Expert)

The role of the Expert Panel was to:

- assist with the procurement to select an expert to undertake the HHRA
- provide advice on the development of the HHRA
- review both the draft and final reports of the HHRA
- provide advice to the CSE regarding the HHRA.

The full terms of reference for the independent HHRA and membership of the Expert Panel is in Appendix 1.

2.1 WHAT IS A HUMAN HEALTH RISK ASSESSMENT?

A HHRA is a process of assessing the potential risk associated with exposure to a hazard on a specific human population, often over a defined period of time (enHealth, 2012). A human health risk is also defined as the likelihood that a given exposure or series of exposures may have damaged or will damage the health of individuals (US EPA, 2016a).

The risk assessment process usually involves:

- issues identification
- hazard identification
- dose-response assessment
- exposure assessment for the identified population
- risk characterisation (enHealth, 2012).

The outcomes of the risk assessment are usually provided to those managing the issue and are a source of information when considering the risk management strategies needed to minimise or prevent the risk from occurring. The risk assessment process requires communication with stakeholders throughout the process to ensure all issues are considered and information assessed is accurate (enHealth, 2012). Figure 1 provides an overview of the risk assessment process.

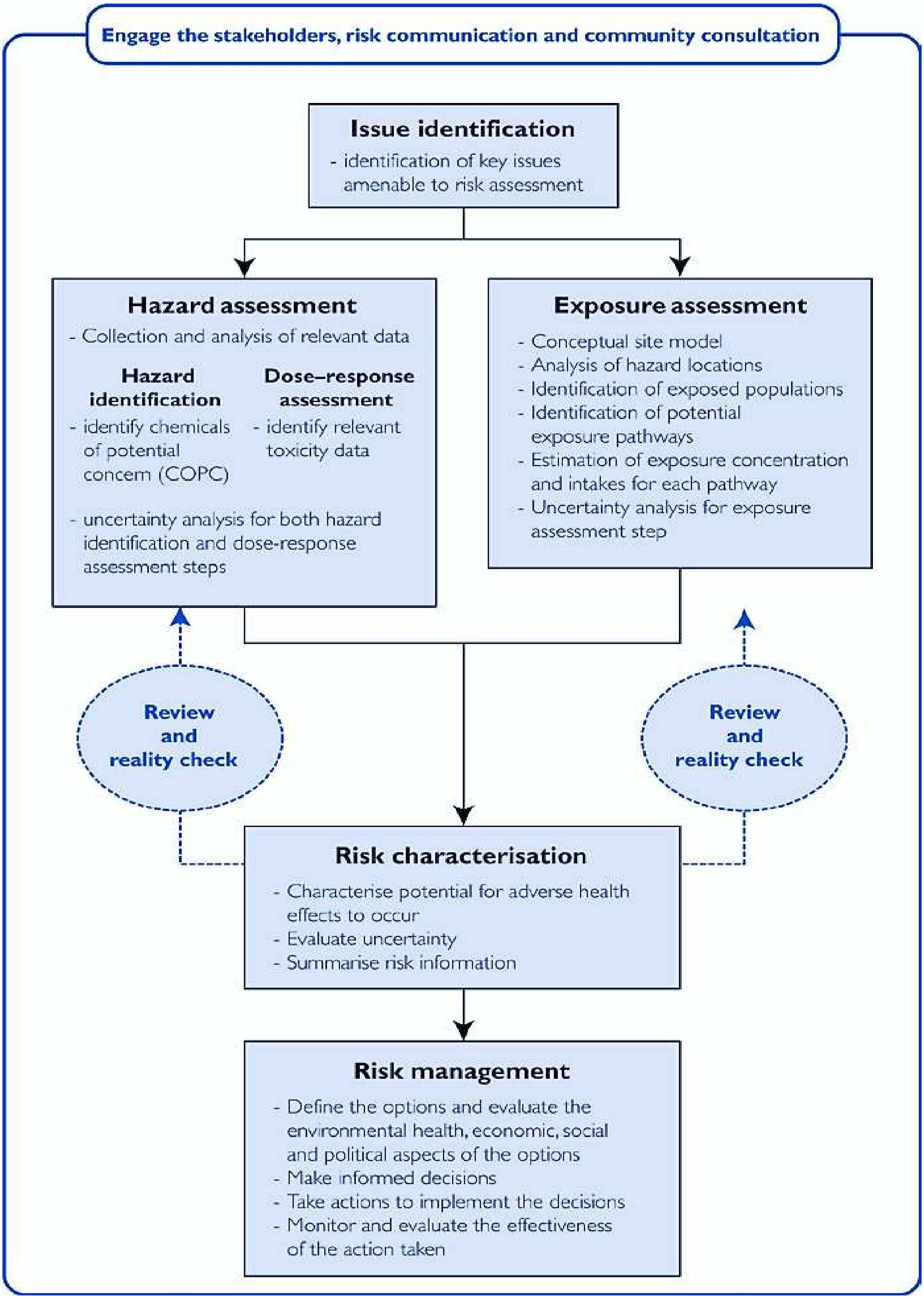

Figure 1: Environment Health Risk Assessment Model[1]

[1] Used by permission of the Australian Government. Environmental Health Standing Committee (enHealth), Environmental Health Risk Assessment: Guidelines for assessing human health risks from environmental hazards, Australian Health Protection Principal Committee, Canberra, 2012.Graphic design by Zoo Advertising, Canberra.

2.2 LORD HOWE ISLAND RODENT ERADICATION PROGRAM

The LHIB proposes to undertake a one-off REP preferably in winter 2017, although should there be the need to delay the REP, approval is also being sort for a three year period to allow it to occur during winter 2018 or 2019 (LHIB, 2016). Since publishing the Public Environment Report, the LHIB has made the decision to delay the REP until winter 2018 should it be approved. It is proposed that the REP will use Pestoff 20R, a cereal-based bait pellet, which contains 20 parts per million (ppm) of the rodenticide brodifacoum. The REP will use in total 42 tonnes of pellets, which equates to 840 g of brodifacoum, over two applications 14 to 21 days apart. The proposed methods for distributing the bait across the island are shown in Figure 2 and Figure 3 (LHIB, 2016). Distribution methods include:

- aerial distribution (green shading on maps)
- hand distribution (purple shading)
- hand distribution with bait stations (blue shading)
- combination of aerial broadcast, hand broadcast and bait stations depending on the finalised property management plans (orange shading) (LHIB, 2016).

Risk mitigation strategies to minimise the impact on the environment and community include:

- captive management of Lord Howe Woodhens and Lord Howe Pied Currawongs, both of which are vulnerable and at risk of poisoning from the rodenticides as determined during the LHI non-toxic bait trial
- removal of dairy cattle and chickens from LHI during the REP
- removal or muzzling of dogs on LHI during the REP.

For more information on the proposed REP refer to the Public Environment Report (EPBC 2016/7703) (LHIB, 2016).

2.3 HOW DOES THE HUMAN HEALTH RISK ASSESSMENT FIT INTO THE RODENT ERADICATION PROGRAM?

The REP requires various Commonwealth, state and local government approvals or assessments (LHIB, 2016), including:

- approval to undertake the REP due to it having an impact on matters of national environmental significance (World and National Heritage place status and impact on threatened and migratory species)
- approval for use of brodifacoum in the manner proposed in the REP
- approval to capture and keep Lord Howe Woodhens and Lord Howe Pied Currawongs during the REP – a threatened species statement and license is also required
- approval to aerial bait within 150 m of a dwelling
- assessment on potential impact on threatened marine species, habitats and the Marine Park
- various approvals from the Civil Aviation Safety Authority for helicopter operations
- NSW Species Impact Statement
- environmental assessment (non-statutory).

The LHIB will make a final decision on whether or not to undertake the REP only once all approvals and assessments have occurred and the recommendations from the independent HHRA are considered (LHIB, 2016).

It should be noted that a previous HHRA was also undertaken, the '2010 HHRA' which looked at the REP on LHI. The agreement to undertake an additional HHRA, covered in this report, was made through discussions between the LHIB and the LHI community through the Community Working Group (LHIB, 2016).

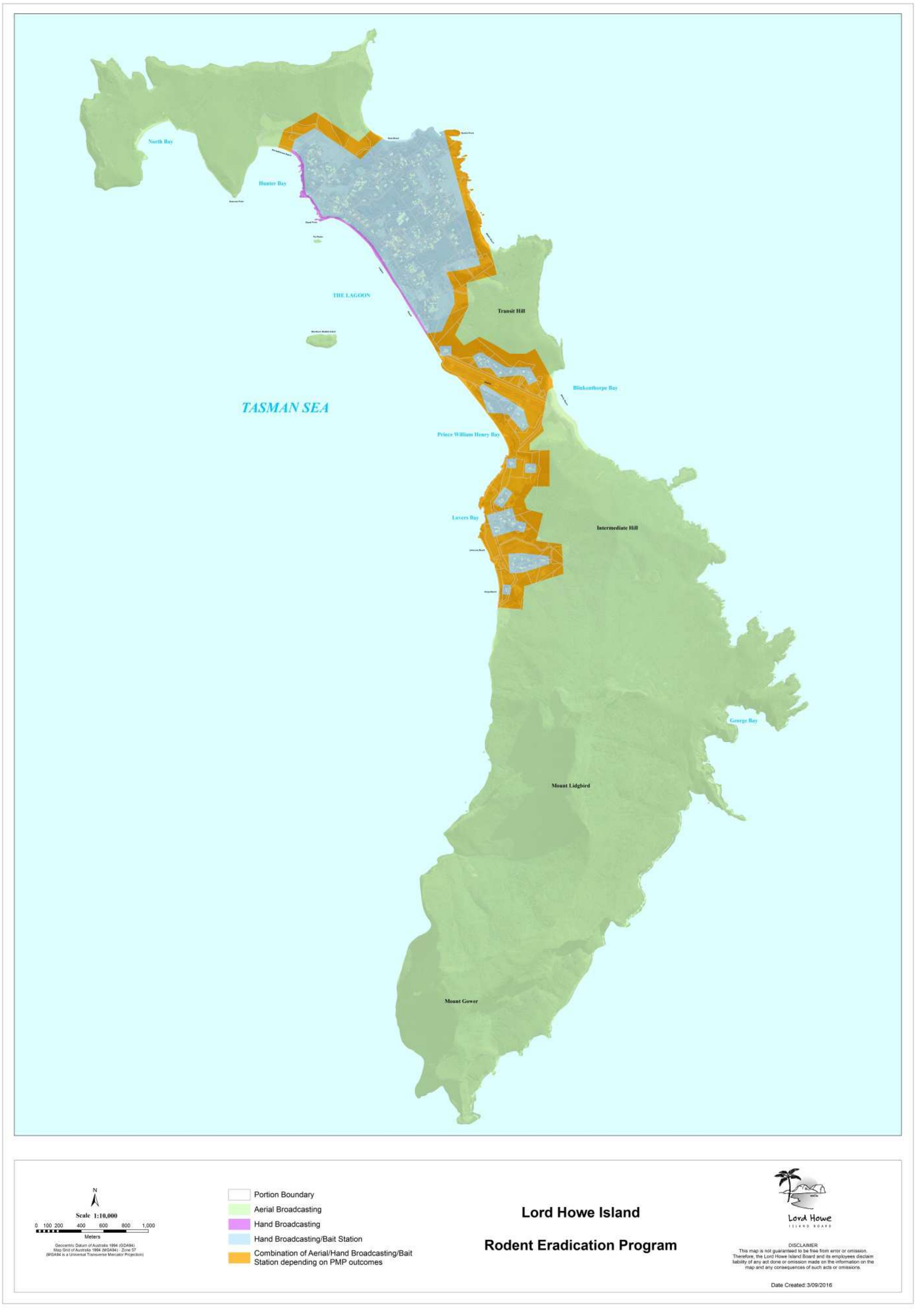

Figure 2: Distribution of Pestoff 20R for the proposed REP – entire island

Figure 3: Distribution of Pestoff 20R for the proposed REP – middle of island

3 DEVELOPMENT OF THE HUMAN HEALTH RISK ASSESSMENT

3.1 PROCUREMENT

The Office of the NSW Chief Scientist & Engineer (OCSE) undertook a procurement process as per the NSW Department of Industry's procurement procedures, to select an appropriate expert to develop the HHRA. To assist with the procurement, the OCSE convened a Selection Committee, which consisted of the Expert Panel as well as two LHI community representatives and a representative of the LHIB. The role of the Selection Committee included:

- review of procurement documents (Request for Quote documents)
- provide input into procurement process
- review and assess responses to the Request for Quote documents
- recommend a preferred supplier.

A Request for Quote package was developed and sent to 11 potential suppliers with experience in conducting HHRAs. These suppliers were identified from a number of sources, particularly from the Commonwealth Department of Health's pre-qualification scheme with experience in HHRA, and suggestions from the Selection Committee[2]. Individuals or organisations that undertook the 2010 HHRA or responded to issues arising from the 2010 HHRA were excluded due to perceived, potential or actual conflicts of interest. Of the 11 suppliers sent the Request for Quote, five submitted a response.

The Selection Committee met twice to discuss the responses. At the conclusion, the Selection Committee agreed to recommend Ramboll Environ Australia Pty Ltd (Ramboll Environ) to undertake the HHRA.

Following the recommendation, the OCSE formally engaged Ramboll Environ to undertake the HHRA of the LHI's proposed REP.

3.2 THE HUMAN HEALTH RISK ASSESSMENT PROCESS

3.2.1 Human Health Risk Assessment Methodology

As required in the Request for Quote, the methodology employed by Ramboll Environ to undertake the HHRA aligned with the methodology described in enHealth's seminal guidance publication entitled *Environmental Health Risk Assessment: Guidelines for assessing human health risks from environmental hazards* (enHealth, 2012). It also aligned with other international guidance documents where relevant. The steps in the HHRA undertaken by Ramboll Environ included:

1. Lord Howe Island description
2. issues identification
3. data review and evaluation
4. hazard assessment
5. exposure assessment
6. risk characterisation, including the developing of environmental criteria
7. sensitivity analysis.

[2] There were no relevant suppliers on the NSW Government major supplier list and while one was listed on the NSW Government pre-qualification scheme, this supplier has an association with the previous HHRA.

3.2.1.1 Lord Howe Island Description

While not a formal step in the HHRA process, Ramboll Environ has provided a description of the island (Appendix 2 Section 2). This assists by identifying any aspect of the island that may need to be considered in the HHRA and provides a basis for developing a Conceptual Site Model (CSM) to assist with the identification of potential human exposure pathways. Information described includes island facilities, the ecology, marine environment and hydrology (including surface and groundwater movement).

3.2.1.2 Issues identification

Issues identification aims to gather information on the items or factors to be addressed in the HHRA, and includes feedback from stakeholders on issues (Appendix 2 Section 3). For the LHI REP HHRA, this has including describing the problem, the current control program and the proposed eradication program. Stakeholders consulted included LHI community, LHIB, OCSE and the Expert Panel.

3.2.1.3 Data Review and Evaluation

Ramboll Environ undertook a data review and evaluation step to ensure all information pertinent to the proposed REP is considered in the HHRA (Appendix 2 Section 4). For the LHI REP this has included:

- identification of reports and literature on brodifacoum, rodent eradications and potential human health impacts
- data gap analysis and proposed strategies to address gaps
- review of the fate in the environment of the chemical
- identification of potential population groups that might be exposed as a result of the eradication program (i.e. human receptors)
- identification of potential exposure pathways.

3.2.1.4 Hazard Assessment

According to enHealth guidelines, hazard assessment involves two steps:

1. hazard identification – that is identification of the chemical(s) that need to be considered in the formal HHRA – in this case, brodifacoum
2. dose-response assessment – collection and analysis of data on the relationship between exposure (‘dose’) and possible toxic effects.

The hazard identification (Appendix 2 Section 5) considered:

- the properties of the hazard (brodifacoum)
- persistence and bioaccumulation of the hazard in the environment (including water and soil)
- the pathway of the chemical through the body
- the effect on humans, including vulnerable or sensitive groups
- the relationship between the proposed mode of action of brodifacoum (inhibition of the blood clotting system) and toxic effects observed in animals and humans at sufficiently high doses. This included consideration of potential effects on reproduction and birth defects, as requested by community input.

The dose-response assessment considered how much of the substance is needed to cause an effect. In the Ramboll Environ report, it is also referred to as reference dose or reference concentration. For this HHRA, Ramboll Environ considered two separate dose-response levels:

- dose-response due to exposure through the pathways from environmental sources identified in the CSM (normal approach in HHRAs)

- dose-response due to direct consumption of pellets (requested by stakeholders), with particular attention to dose estimates that could result in harm to children.

In considering a dose-response level due to exposure through the environment, Ramboll Environ calculated the value based on a No Observable Effect Level (NOEL), the standard approach in HHRAs. The NOEL is the highest concentration of the chemical where no effect has been observed in studies or trials. Ramboll Environ used a NOEL determined through an oral toxicity study in rats, 0.001 mg/kg of body weight/day. This NOEL has been used in other assessments of brodifacoum. Various safety or uncertainty factors are then applied to the NOEL to account for differences within a species (sex, health status, nutritional status and metabolism), differences between species (animals to humans) and other factors such as exposure duration and data quality. This results in an estimate of a tolerable dose that is at least two orders of magnitude below the NOEL, at which even sensitive individuals in the study have not responded. Different dose response levels were then calculated for exposure through ingestion, through the skin and via inhalation.

Ramboll Environ was also requested to consider exposure due to direct ingestion of a pellet. For this, the dose response was based on a level where an effect has been observed. Since, it is expected that infants and young children are most at risk of direct ingestion, a dose response level was only calculated for these groups.

3.2.1.5 Exposure assessment

Exposure assessments estimate the amount of the chemical that may be present in the different environmental sources (water, soil, air, food) and estimate the amounts that may be transmitted via the identified pathways. Factors that could impact on exposure for each of the different population groups is also assessed at this point.

For each of the exposure pathways, Ramboll Environ calculated how much might be expected in each of the different media (Appendix 2 Section 6). Media assessed included:

- soil, sand and sediment
- ground, surface and tank water
- air
- seafood
- fruits and vegetables.

For each of the population groups, Ramboll applied known reference values, for factors that impact on exposure, including:

- body weight
- exposure duration
- drinking water and soil ingestion
- dermal contact with soil
- dust inhalation
- consumption of food
- surface water exposure
- sediment exposure.

Most of the reference values used in the exposure assessment were sourced from the enHealth guidelines (enHealth, 2012). Where appropriate reference values were not included in these guidelines, reference values from guidelines published by the US Environmental Protection Agency were used (US EPA, 2011).

3.2.1.6 Risk Characterisation

Risk characterisation brings together the entire information gathered in the HHRA process to give an estimate of the risk. For each population group, a risk estimate or hazard quotient is calculated for each exposure pathway. This is a ratio of the estimated intake or exposure for that pathway to the dose response (or reference dose/concentration). For each of the population groups, the hazard index is then calculated which is the sum of all hazard quotients for the population group (Appendix 2 Section 7).

The hazard index and hazard quotients are presented as a number:

- zero – no exposure
- one – exposure at the NOEL level
- above one – exposure above the NOEL.

Ideally, hazard index and hazard quotients should be below one meaning that for each of the exposure pathways and all exposure pathways combined, exposure is below the NOEL and no adverse health effects are expected. Values above one mean that exposure has exceeded the highest level where no observed effects are expected, and while adverse health effect may still not occur, the conservatism built into the HHRA process is eroded and risk management strategies may be warranted to minimise the potential risk.

Ramboll Environ was further requested to consider:

- the risk of a toddler or school child ingesting the pellets (number consumed to produce an observable effect)
- the risk should the proposed REP not proceed – risk associated with the existing rodent control programs continuing *ad infinitum*, using brodifacoum and other rodenticides
- potential criteria that could be used to monitor different media during the proposed REP

3.2.1.7 Sensitivity Analysis

The final step of the HHRA is to undertake a sensitivity analysis. Given that the risk characterisation is theoretical and based on some assumptions, the sensitivity analysis considers what variables contribute most to risk and may need further refinement, through either collection of further data or the development of risk management strategies.

For the proposed REP, sensitivity analysis was conducted using the toddler population group and those pathways contributing most to exposure, that being soil ingestion, dermal contract with skin and ingestion of tank water for potable use.

3.2.2 Community Consultation on Human Health Risk Assessment

To ensure the HHRA addressed concerns from the LHI community, two community consultation activities were undertaken.

Representatives from the OCSE and Ramboll Environ visited LHI and held two community meetings. The purpose of these meetings was:

- to provide the community with information on how the HHRA will be conducted
- to provide an opportunity for the community to discuss the content of the HHRA, ensuring their issues are considered in the report.

The OCSE also provided the community with an opportunity to make public submissions into the HHRA (OCSE, 2016). Four submissions were received and have been summarised in Appendix 3.

Comments relating to the HHRA noted the need to ensure all potential pathways are included in the HHRA, particularly:

- all locally produced foods (e.g. seafood, meat, milk, eggs, fruit and vegetables)
- potential for pellets or dust from the pellets present in water source
- direct exposure to dust from the pellets

- ingestion of pellets by children.

It was also noted that the HHRA should consider the most up to date literature and comments from the review of the 2010 HHRA Report. Other comments noted the need to consider both short and long-term health effects associated with brodifacoum and the bioaccumulation of brodifacoum up the food chain, which was undertaken for seafood, fruits and vegetables.

Submissions also raised other non-human health issues associated with the REP, including:

- the level of evidence of a problem
- the risk and benefit of the REP and of the status quo
- justification and legality of the proposed bait distribution methods
- alternative approaches other than the use of brodifacoum.

Feedback was sought from the LHIB on the non-human health issues raised during the community consultation for the HHRA. In response, the LHIB indicated that many of the issues had been addressed by the LHIB in the Public Environment Report (LHIB, 2016) or had previously been discussed with the community through the Community Working Group.

A summary of the submissions was provided to the Expert Panel for review and discussion, see further information at Section 6 and Appendix 3.

4 OUTCOMES OF THE HUMAN HEALTH RISK ASSESSMENT BY RAMBOLL ENVIRON AUSTRALIA PTY LTD

4.1 OVERVIEW OF THE HUMAN HEALTH RISK ASSESSMENT

As previously mentioned Ramboll Environ followed the methodology described in the enHealth guidelines (enHealth, 2012) when conducting the HHRA. In addition, Ramboll Environ considered the possible ingestion of Pestoff 20R pellets, especially for toddlers and schoolchildren, commented on the risk associated with maintaining the status quo (i.e. on-going control program) and developed some criteria for monitoring different environmental media. A copy of the HHRA report is provided in Appendix 2 and below is some of the key information extracted from the report.

4.1.1 Exposure Pathways and Populations

Table 1 provides an overview of the main population groups and exposure pathways considered in the HHRA. The population groups identified were those that are likely to be more sensitive to brodifacoum exposure and subsequently more at risk, that being toddlers, school children and pregnant females. The HHRA also considered adults including visitors to the island who may spend considerable time outside. Elderly people, including those prescribed warfarin therapeutically were encompassed by the adult category, as the choice of the lowest toxicity reference value would account for any particular sensitivity they may have.

Table 1: Exposure pathways included in HHRA

Exposure Pathway	Toddler	School Child	Pregnant Female	Adult
Incidental ingestion and dermal contact with soil beneath/adjacent to a degraded pellet	√	√	√	√
Outdoor inhalation of dust derived from pellets during aerial and hand broadcasting distribution	√	√	√	√
Ingestion of locally caught seafood	√	√	√	√
Ingestion of locally grown vegetables and fruit	√	√	√	√
Ingestion of meat, dairy and poultry products	x	x	x	x
Ingestion of tank water/groundwater as drinking water	√	√	√	√
Direct contact and incidental ingestion of surface water	√	√	√	√
Direct control and incidental ingestion of creek sediment	√	√	√	√
Direct ingestion of Pestoff 20R pellet	√	√	√	√
Dermal contact with Pestoff 20R pellet	√	√	√	√
Exposure via pets	x	x	x	x

Ramboll Environ considered all possible pathways including those suggested by the community, with only a few being omitted due an incomplete pathway:

- ingestion of meat, dairy and poultry products – during the REP all meat cattle and poultry will be removed from the island and milk from the dairy cattle will not be consumed. As such, exposure through these pathways is not possible.
- exposure via pets – exposure to brodifacoum due to contact with pets was considered low when compared to exposure through incidental ingestion and dermal contact with soil. This pathway was considered as part of the assessment of incidental ingestion of soil.

4.1.2 Dose-Response Values

To assist with characterising the risk, Ramboll Environ developed a number of dose-response values or reference doses (Table 2 and Table 3). As mentioned previously dose-response values for oral, dermal and inhalation exposure (Table 2) were developed based on a NOEL, meaning that exposure at this level is equivalent to the highest concentration where no effect was observed. This value was used for oral exposure and then further adjusted for dermal and inhalation exposure.

Table 2: Adopted dose-response values for brodifacoum

Reference dose – oral	0.0000033 mg/ kg bw/day[a]
Reference dose – dermal	0.0000025 mg/ kg bw/day[a]
Reference concentration – inhalation	0.000012 mg/m^3

[a] milligrams per kilogram of body weight per day

The reference dose for pellet ingestion was calculated using a value that could result in an adverse effect in toddlers or schoolchildren (Table 3). While the dose-response level when assessing environmental exposure was based on the NOEL, this level on the other hand is the lowest dose at which an effect is observed.

Table 3: Accidental ingestion of bait

Population Group	Dose to reach adverse effect (mg)
Toddler	0.23
School Child	0.53

4.1.3 Risk Characterisation – Hazard Quotient and Hazard Index

For each of the potential exposure pathways, a hazard quotient estimate has been determined (Table 4). As mentioned previously, the individual hazard quotients are added together to obtain a hazard index for each population group (Table 5). The hazard index is less than one for all groups, which means that the potential exposure from all pathways combined is below a level recognised as safe and no adverse effects are expected.

Table 4: Hazard Quotient estimates

Exposure Pathway	Toddler	School Child	Pregnant Female	Adult
Incidental soil ingestion	0.2	0.083	0.027	0.023
Dermal contact with soil	0.094	0.072	0.07	0.065
Inhalation of outdoor dust during aerial distribution	0.026	0.065	0.1	0.1
Dermal contact with surface water	0.005	0.0036	0.0034	0.0033
Incidental ingestion of surface water	0.000028	0.000023	0.0000031	0.0000027
Dermal contact with sediment	0.14	0.11	0.00083	0.00076
Incidental ingestion of sediment	0.0071	0.0029	0.0016	0.0014
Ingestion of fruit and vegetables	0.051	0.021	0.026	0.026
Ingestion of seafood	0.036	0.02	0.019	0.016
Ingestion of tank water for potable purposes	0.30	0.17	0.44	0.33

Table 5: Hazard Index for the different population groups

Population Group	Hazard Index
Toddler	0.86
School Child	0.54
Pregnant Woman	0.69
Adult	0.57

Ramboll Environ used protective assumptions to estimate exposure, and therefore hazard quotients. Calculating the risk associated with exposure scenarios includes facing uncertainties, where uncertainties were recognised, Ramboll Environ employed a "protective approach and assumptions are adopted in order that the final results are expected to overestimate rather than underestimate potential exposures and risks" (p16). The influences of mitigation procedures, and their potential to limit or avoid exposure, have not been included in these exposure calculations. An example of this is the calculation of potential brodifacoum concentrations in potable tank water (Figure 4).

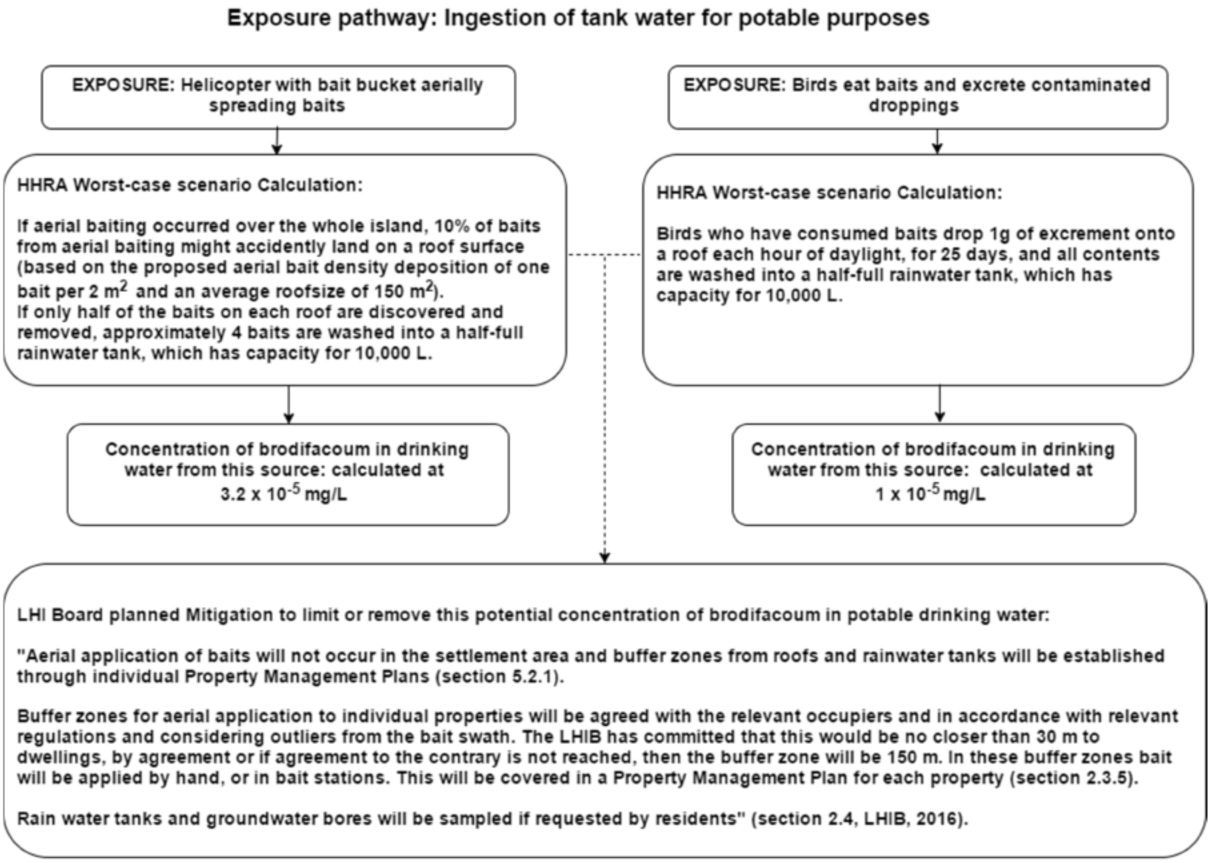

Figure 4: Exposure pathway and calculations for ingestion of tank water for potable purposes in the Ramboll Environ Report, as well as mitigation measures in the LHIB Public Environment Report

4.1.4 Risk Characterisation – Ingestion of Baits

As there is a potential, particularly for children, to ingest baits, the number of baits needed to result in an adverse effect was calculated for toddlers and schoolchildren (Table 6). Depending on the age group and pellet size, the number needed to be ingested to result in an adverse effect ranged from 5.6 to 44.5 over a period of up to two days.

Table 6: Number of pellets need to result in an adverse effect

Group	Number of 10 mm Pestoff 20R pellets	Number of 5.5 mm Pestoff 20R pellets
Toddler	5.6	13.4
School child	18.8	44.5

4.1.5 Risk Characterisation – Not Proceeding with REP

The HHRA also considered the risk should the REP not proceed and current rodent control programs continue, and noted:

- there is potential exposure to rodenticides in soil, water and food under both the current control program and the REP
- as the current control program uses less rodenticide, any risk using the same rodenticide is not likely to be greater than that identified for the REP
- the current control program may result in rodents developing resistance to the rodenticides and a new rodenticide may be needed at a later stage, the risk of which is unknown
- an ongoing control program will result in potential risks also being ongoing.

4.1.6 Environmental Criteria

As requested, Ramboll also proposed some environmental criteria should there be the need to monitor the different environmental media prior or during the REP (Table 7). These levels were calculated based on the most sensitive population, that being toddlers. The criteria have been calculated so that a person does not exceed the NOEL and has taken into account potential exposure through all pathways for that media.

Table 7: Proposed environmental criteria

Media	Criteria
Soil	0.068 mg/kg
Sediment	0.047 mg/kg
Surface water/Groundwater	1.1×10^{-5} mg/L
Seafood (edible flesh)	0.45 mg/kg
Tank water	1.4×10^{-4} mg/L

4.1.7 Sensitivity Analysis

The sensitivity analysis identified that consumption of tank water was the only exposure pathway where the overall hazard index changed significantly due to pellets present on the roof ending up in the water tank. The more pellets present the higher the rating. Based on this, the HHRA Report notes that minimising pellets from landing on roofs, and their removal should they be present is a priority in managing this exposure pathway.

4.2 CONCLUSIONS FROM THE HUMAN HEALTH RISK ASSESSMENT

The HHRA concluded that exposure is below that likely to result in adverse effects to any individual.

The report noted that the pathways that contributed most to potential exposure include:

- ingestion of soil (directly beneath the pellet)
- ingestion of tank water (pellet landing on roof)
- dermal contact with sediment or sand (directly beneath the pellet)
- inhalation of airborne dust.

The HHRA also assessed potential ingestion of Pestoff 20R pellets by children and concluded that ingestion of one or a few pellets would not results in observable anticoagulant effects.

The conclusion notes that the assumptions made in the risk assessment were conservative (i.e. worst-case scenario) and that the management strategies proposed in the REP will assist with mitigating exposure.

5 RODENT ERADICATIONS AND RODENTICIDES – BACKGROUND INFORMATION

5.1 RODENT ERADICATIONS

This section provides a summary of available information on rodent eradications undertaken internationally to date. More detailed information on rodent eradication programs using the Database of Islands and Invasive Species Eradications (DIISE[3], DIISE, 2015) is presented in Appendix 4.

According to the DIISE database, there have been 1,424 successful[4] eradication programs spanning 925 islands and 55 species, including rodents, ungulates (goats, pigs, etc.), cats, rabbits, birds, reptiles, dogs, etc. Specific to rodents, there have been 875 single eradication attempts, some of which involved multiple species, on 724 islands worldwide. A total of 645 (74%) of these attempts have been classified as successful across 577 islands.

The majority of programs (86%) used toxicants as the primary method of rodent eradication, with most using a single method of deployment. Some eradication programs used a combination of aerial and other deployment (e.g. aerial and bait station), which appears to lead to a higher rate of success than aerial alone.

Brodifacoum was by far the most common primary toxicant used for all methods of toxicant eradications, covering 73% of all operations. Of these 79% are reported to be successful[4]. For aerial baiting on inhabited islands, 17 of 18 attempts used brodifacoum. Of these, 13 were successful (76%), two failed (12%) and the rest are either planned (including Lord Howe Island), in progress or to be confirmed.

5.1.1 Human Health

In spite of island rodent eradications being quite common worldwide, only around 6% of these eradication attempts using toxicants were undertaken on islands inhabited by more than 10 people (DIISE, 2015). As well as the increased risk of reinvasion of rodents due to traffic to and from the island, the additional social dimension complicates eradications on populated islands, as there is a need to consider how the operation will affect humans and their animals (Ogden & Gilbert, 2009; Oppel, Beaven, Bolton, Vickery, & Bodey, 2011).

Fregate Island in the Seychelles is a large inhabited island with agricultural animals, and a permanent population of 214 people. An unsuccessful attempt to eradicate the Norway rats occurred in 1995-1996 using bait stations and snap traps. This was followed by a second successful attempt in 2000 using aerial baiting with brodifacoum.(DIISE, 2015)

Further information on rodent eradication programs, including those on inhabited islands, can be found in Appendix 4. Few examples of detailed HHRAs were found for the eradication programs examined in Appendix 4. Below are two case studies where health and wellbeing risks and mitigations were considered.

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[3] The DIISE is a publicly available web resource providing detailed information on individual eradication projects undertaken globally. The DIISE was co-developed by Island Conservation (a not-for-profit organisation based in the USA), Coastal Conservation Action Laboratory (University of California, Santa Cruz), International Union for the Conservation of Nature and Natural Resources (IUCN) Species Survival Commission (SSC) Invasive Species Specialist Group, University of Auckland and Landcare Research New Zealand.

[4] Success is commonly defined as no further sign of rodents over two rodent breeding periods (Pacific Invasives Initiative, 2016), the DIISE database includes older records which may define success differently.

Case Study 1: Macquarie Island Pest Eradication Project (Parks and Wildlife Services Tasmania, 2015)

During 2010-11, Parks and Wildlife Services Tasmania undertook an eradication project on Macquarie Island targeting rats, mice and rabbits. The project used Pestoff 20R broadcasted both by hand and aerially. While Macquarie Island did not have permanent residents on the island, approximately 35 staff remained on the island during the operation. No exclusion zones were established over the island except for the pilot avoiding dropping bait into the larger lakes. Aerial broadcast occurred over buildings, including staff living quarters.

Prior to undertaking the project, a detailed Environmental Impact Statement (EIS) Report was undertaken. The EIS found that the actual risk to staff was low with the main potential exposure through water supply or direct poisoning. Some of the strategies implemented to manage risk included:

- prior to the broadcast
    - water supply dam was disconnected and flushed before the bait drops
    - roof water collection systems were disconnected
- during the broadcast
    - a trained doctor was on site with ample Vitamin K antidote on hand
    - water was filtered
- after the broadcast
    - staff were screened for coagulopathy at monthly intervals
    - prior to reconnecting the water supply, staff manually removed bait pellets
        - from roofs and guttering
        - in and within one metre of the creek and dam

Case Study 2: Island of South Georgia Rodent Eradication Program (South Georgia Heritage Trust, 2010; Government of South Georgia and the South Sandwich Islands, 2017)

Island of South Georgia, a British overseas territory, commenced the first phase of a rodent eradication program in 2011. The Island of South Georgia is in the Southern Atlantic Ocean with a small settlement, Grytviken, of around 20-30 people in summer. The program included aerial baiting with brodifacoum across most of the island with hand broadcast in and around buildings and other structures.

As Environmental Impact Assessment conducted prior to Phase one addressed potential effects on human health, soil and water quality. While the risk to human health was deemed low, to protect soil and water supplies, the following risk mitigations strategies were implemented:

- station water system was flushed and checked to ensure the water intake pipe didn’t pick up sediment, which could be contaminated
- all people on the island were informed of the baiting/broadcast
- tourists were not allowed during the baiting/broadcast
- the medical officer was supplied with Vitamin K
- baits were not dropped on freshwater lakes
- rodent carcasses were removed within 20m of the water supply
- bait was removed from and within 2m of the main water systems.

5.1.2 Elements Contributing to Success or Failure

A major concern in undertaking any rodenticide based eradication program is the potential for failure, resulting in repeated attempts and further exposure of humans and non-target species to rodenticide.

Eradication programs can fail for a wide variety of reasons including failure to reach all rodents through inadequate bait availability, low bait palatability, insufficient bait toxicity, toxicant tolerance, bait competition, alternative food sources, not gaining access to all properties on the island to undertake baiting and reinvasion (Holmes, Griffiths, Pott, Alifano, Will, Wegmann, & Russell, 2015). Mice eradications have a higher failure rate than rat eradications, with two reviews suggesting inadequate bait density on the ground may be a significant factor in failure (Howald et al., 2007; MacKay, Russell, & Murphy, 2007). The LHIB will attempt to target both rats and mice for eradication by maintaining a baiting density of at least one large bait pellet per two square metres for aerial broadcasting and in the settlement area, one small bait pellet per half square metre for hand broadcast and approximately 10 m spacing for bait stations (LHIB, 2016).

While mammal eradication projects on inhabited islands using brodifacoum via aerial drop is less common than on uninhabited islands, there are many cases of successful programs (Oppel et al., 2011). The islands being targeted are getting increasingly larger and potentially more populated, as ecosystem restoration attempts to move from uninhabited to inhabited locations and methods improve (Campbell et al., 2015).

5.2 BRODIFACOUM

5.2.1 Cases of Brodifacoum Ingestion in New South Wales

The NSW Poisons Information Centre (NSW PIC) receives approximately 200,000 calls annually, which is approximately 50% of all poisoning-related calls in Australia. The NSW PIC receives calls from New South Wales, Tasmania and the Australian Capital Territory on a near full-time basis and a shared after-hours service to the remainder of Australia.

At the request of OCSE, the NSW PIC manually reviewed all cases involving long acting anticoagulant rodenticides. While the number of calls received is made public in annual reports, manual data extraction provided the unique episodes of exposure. The details provided in the manual data extraction are as reported by the caller. The number of exposures reported to the NSW PIC for long acting anticoagulant rodenticide (including brodifacoum), first generation anticoagulants (including warfarin), and unidentified rodenticides for the period 2004 to 2015, is shown in Appendix 5.

In 2013 incidents reported to the NSW PIC involving long acting anticoagulant rodenticides, including brodifacoum, totalled 256 and ranked as the 78th highest substance receiving calls (information provided by NSW PIC). The majority of cases involved children (ranked as 39th) compared to adults (ranked as 218th). The highest ranking substance in the same year was Paracetamol, which received a total of 5,316 calls; 2,245 of these calls involved children.

Detailed information specifically for incidents of brodifacoum exposure was provided for the two year period from July 2014 to June 2016. This information included a detailed breakdown of ages and exposure types. All routes of exposure were investigated, including: ingestion, dermal, inhaled, and parenteral (by some route other than through the alimentary canal). The NSW PIC does not routinely follow up calls to obtain outcome data, although all deliberate self-poisonings are assessed for mental and medical health in hospital.

There were 537 unique incidents related to actual and suspected exposure to brodifacoum in the two years, of these 486 were accidental. A total of 319 of these cases were identified as definite exposures, of which the majority were identified as definite exposures through ingestion (300 cases, 62% of the total of all accidental cases).

Of these accidental, definite exposures from ingestion of brodifacoum, the main age group were 1-4 year olds (226 cases). Within this age group, the most susceptible age were one year olds (121 cases, with an additional 10 cases reported within the age group of one to four). The human receptors of concern included for risk estimation in the Ramboll Environ report included the following age groups: toddlers (2-3 years old), schoolchildren (8-11 years), and adults (>18 years). No cases involving children aged between 8-11 years accidently ingesting brodifacoum were reported by the NSW PIC. The breakdown of the number of cases involving definite ingestion of brodifacoum into other age categories is shown in Figure 5. Toddlers were also the main age group showing accidental dermal exposure, although the number of incidences (8 cases) was much lower than ingestion.

The amount ingested was self-reported by the caller, NSW PIC did not verify amounts. Of the total definite accidental ingestions over all age groups: five were unknown, 135 tasted or chewed a partial pellet, 86 ate half a pellet to two pellets, five ate between three and six pellets; a further 69 cases reported other amounts (Figure 6).

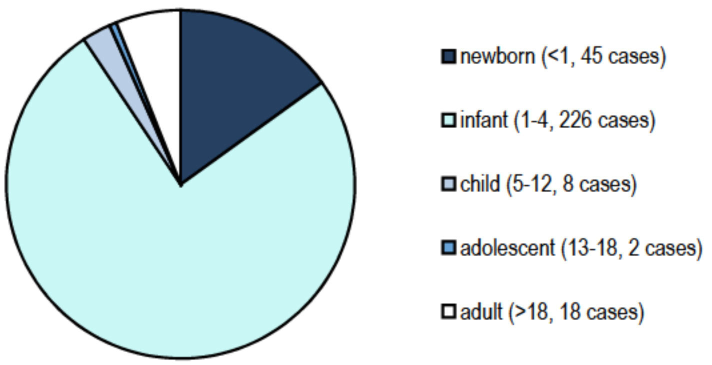

Figure 5: The number of cases from July 2014 to June 2016 involving definite and accidental ingestion of brodifacoum by age category

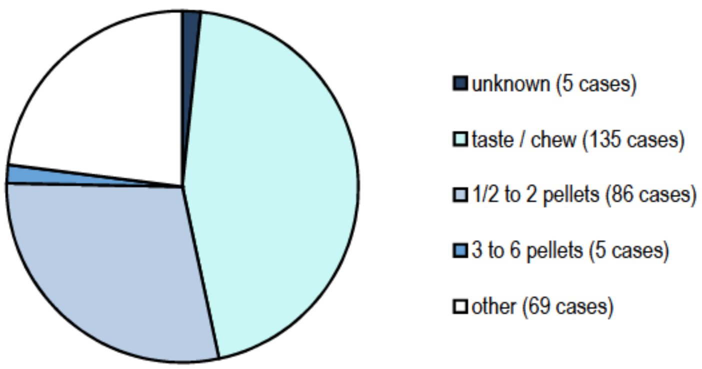

Figure 6: The amount of ingested brodifacoum reported to the NSW PIC from July 2014 to June 2016

Of all patients accidently and definitely exposed to brodifacoum, three were referred to hospital; an additional two with suspected exposure were also referred. A large proportion of calls were from the home and were handled as stay at home cases (270 cases, 85%), others were from hospitals or from a general practitioner's surgery (45 cases, 14%) where presumably the patients were taken prior to calling the NSW PIC.

A total of 11 patients accidently exposed through any exposure pathway reported symptoms at the time of the call, eight of these were from definite exposure to brodifacoum. These symptoms were listed as vomiting, nausea, headache and hypertension, swollen lips and eyes, and a tingling sensation. NSW PIC notes that it is not known whether some of these symptoms are related to brodifacoum exposure. Ramboll Environ in the HHRA Report refer to clinical reports of poisoning symptoms in section 5.1.5 of their report.

The NSW PIC has informed OCSE that no incidents involving brodifacoum have been reported from Lord Howe Island in the two year period from July 2014 to June 2016.

5.2.2 Regulations on the use of Brodifacoum

Both within Australia and internationally, the use of anticoagulant rodenticides, including brodifacoum is tightly regulated. In Australia, substances controlling, inhibiting or destroying rodents are considered to be pesticides (Australian Government, 2016). Each brand and product needs to be registered by the Australian Pesticides and Veterinary Medicines Authority (APVMA) prior to being available for sale. The registration process includes an assessment of the potential impacts of brodifacoum on the environment, human health and trade, and its effectiveness based on its method of use (NSW EPA, 2016). As at December 2016, there were 62 products containing brodifacoum approved for use in Australia (APVMA, 2016b). Types of products approved for household includes wax blocks, throw packs and bait stations all of which contain brodifacoum at a concentration of 50 mg/kg (APVMA, 2016b).

Australian regulatory bodies can grant permits for the use of pesticides, including brodifacoum, contrary to the label instructions ('off-label'). These permits, such as a 'Minor Use Permit', are for a specific situation or use, over a specific time and will usually include conditions for use (APVMA, 2016a).

NSW state regulatory bodies control pesticide use. The Environmental Protection Authority (EPA) regulates pesticide use in NSW for agriculture, public lands, commercial or domestic premises (NSW EPA, 2016). Veterinary chemicals are regulated by the Department of Primary Industries (NSW EPA, 2016). Local Land Services are responsible for control of pest animals and the supply and distribution of pesticides for vertebrate pests, plague locusts and wingless grasshoppers (NSW EPA, 2016).

Pesticide regulations differ between countries. The USA restricts consumer use of first-generation anticoagulant rodenticides to ready-to-use bait stations only, and second-generation anticoagulant rodenticides to professional and agricultural use only (US EPA, 2016b, 2016c). The USA permits the use of brodifacoum for island eradication programs provided all federal, state and local permits are obtained (U.S. Fish & Wildlife Service, 2013).

6 EXPERT PANEL – REVIEW OF THE HUMAN HEALTH RISK ASSESSMENT

6.1 HHRA REPORT

The HHRA Report provides a comprehensive assessment of potential human health risk associated with the proposed LHI REP. In reviewing the report, the Expert Panel:

- supports the exposure pathways and populations assessed in the HHRA
- supports the approach taken to develop the reference doses
- notes the calculated hazard indices for the different populations assessed
- based on the information in the report, agrees with the conclusion that the expected exposure is below a level derived as safe and that adverse health effects would not be expected from brodifacoum exposure due to the REP

The Expert Panel notes that the HHRA Report has quantified potential risks and that while no significant risks have been identified from exposure to brodifacoum during the REP, the LHI community may still wish to minimise exposure. This could be achieved by avoiding exposure through those pathways that contribute most to exposure, which were:

- ingestion of soil (directly beneath the pellet)
- ingestion of tank water (pellet landing on roof)
- dermal contact with sediment or sand (directly beneath the pellet)
- inhalation of airborne dust.

Strategies that could be implemented to assist minimising exposure include:

- washing hands and face after working or playing outside
- monitor and remove any pellets that land on roofs, with any monitoring and removal activity undertaken in a safe and careful manner
- wear covered shoes outside
- during aerial baiting, avoid areas where aerial baiting is occurring.

This avoidance is not mandatory as the HHRA did not identify the potential for adverse effects, and has only been suggested to assist those who may be concerned about exposure.

6.2 PUBLIC HEALTH

During community consultation, other health issues were identified. In addition, in a submission made to the OSCE issues relating to mental health of the island residents were noted (see Appendix 3). Ramboll Environ in the HHRA Report also noted that during the community consultation sessions, residents expressed concern about stress and anxiety with the REP. While worries about chemical exposure may be contributing to these concerns, other factors such as financial, societal, family and personal factors were also noted. Stress, anxiety, and other issues around wellbeing are generally not considered within a HHRA, they are issues that are within the public health field.

Public health can be defined as “the art and science of preventing disease, prolonging life and promoting health through the organized efforts of society” (WHO, 2016). Public health encompasses all aspects of health and wellbeing, including mental health. The emergence of stress and anxiety within communities dealing with environmental risks is not uncommon and has been observed by the OCSE when engaging with communities during the Williamtown RAAF Base contamination incident and during the Independent Review of Coal Seam Gas (CSG) activities (Taylor, Sandy, & Raphael, 2013).

Psychological and wellbeing impacts have been explored in an Expert Paper developed by Taylor, Sandy & Raphael (2013) for the Independent Review of CSG. Often these health impacts are not directly related to the chemical hazard, but to other concerns regarding the issue, be they perceived or real (Taylor et al., 2013). Depending on the level of trust and communication between the parties, impacts on psychological and mental health may increase and decrease, and in worst-case scenarios may manifest in significant health impacts. These health impacts may be exacerbated by people feeling a loss of control over their environment (including home) or that their concerns are not being seriously considered (Taylor et al., 2013).

Addressing issues concerning psychological and wellbeing requires considerable experience and expertise. Community engagement may assist, although health services would be required for those with serious issues. Consultation and engagement with the health professionals may assist with identifying strategies to assist in addressing community concerns.

6.3 GENERAL OBSERVATIONS

Other issues were noted during the community consultation activities, most of which are summarised in Appendix 3. These issues include:

- use and distribution of brodifacoum
- impact on wildlife
- cost and benefit of the proposed REP
- liability or compensation should the REP have unintended consequences.

Many of these issues and concerns have been covered during the planning for the REP and are elaborated within the Public Environment Report, published as a requirement for the environmental approval process (LHIB, 2016), and the Economic Evaluation Report (Gillespie Economics, 2016). Some of the activities and planning that has occurred include:

- establishment of a Project Steering Committee consisting of representative from Department of Environment (Commonwealth), Office of the Environment & Heritage, LHIB and a rodent eradication expert to oversee the implementation of the REP
- establishment of a Scientific & Technical Advisory Committee to provide expert scientific advice
- establishment of a Community Working Group to enhance engagement and consultation with the community
- technical assessment of alternative rodent eradication techniques and toxicants
- review of potential impacts on relevant flora and fauna during the proposed period (July to August)
- non-toxic bait trials to assess uptake by rodents and non-target species resulting in the decision to develop a captive management plan for the LHI Woodhen and LHI Currawong
- trial of the aerial baiting operations to assess methodology
- trial of the captive management plan for LHI Woodhens and LHI Currawong
- economic evaluation of the REP.

The LHIB appears to have addressed many of the issues noted by the community, although some in the community appear unaware of this. Community consultation and engagement can be difficult. Not all people respond to the same method of communication and peoples' interest waxes and wanes depending on their individual circumstances. People may seek further information from different sources for a variety of reasons, which may result in messages being misinterpreted and feedback not reaching the decision makers. During any community consultation and engagement exercise there is always the need to assess consultation and engagement techniques to ensure information reaches and remains relevant to the community. The establishment of the Community Working Group in 2014 may have assisted with improving community engagement, although it would be worth monitoring to ensure information is reaching the greater community. It is noted that there remains concern with some in the community and continual assessment and refinement of communications strategy may be warranted. This should include ensuring information on the proposed REP is clear and unambiguous, such as descriptions of the distribution methods that will occur across the island.

Some within the community have raised the success of the REP and how this will be measured as a concern. Monitoring the rodent population post-eradication will provide a measure of success, and indicate whether further control efforts will be required. The proposed rodent detection monitoring program is planned to commence monitoring four weeks after the REP has occurred (LHIB, 2016). Proposed methods include detector dogs, trail cameras, chew blocks or wax trays, traps and tracking tunnels (LHIB, 2016). Should rodents be detected during the monitoring, strategies will be deployed to remove surviving individuals (LHIB, 2016).

Resistance to the rodenticide has also been raised as a concern. This has been reviewed by the LHIB in the Public Environment Report, which notes:

- resistance will be an issue should the on-going control program continue
- resistance trials using rats and mice from LHI indicate rats should not develop resistance, while mice may
- further work may be needed to establish how widespread the resistance is and if necessary develop additional eradication strategies for mice (LHIB, 2016).

If rats do re-emerge on the island, due to a less than 100% eradication or reintroduction, they will be at reduced population numbers. New technologies such as sterilants, currently being developed and not yet commercially available, could potentially be used in the future to control rodents.

Monitoring and planning of fall-back approaches should continue to be explored in case the REP does not lead to full eradication or unforeseen outcomes arise.

6.3.1 Examination of Alternative and Emerging Technologies for Rodent Eradication

There has also been considerable interest in other technologies for rodent eradications and the OCSE has developed a table of some of the main emerging technologies (Appendix 6). The OCSE also engaged experts from the Priority Research Centre in Reproductive Science, University of Newcastle, to develop a position paper (Swegen, Zamira, & Aitken, 2017) on the potential application of emerging technologies for rodent eradications, this paper will be available on the Office of the NSW Chief Scientist & Engineer website.

The position paper provides a review of novel and emerging strategies for rodent eradication, with a focus on fertility interventions and sterilants, including immunocontraceptives and gonadotoxicants. While many of these are still in development, some have potential to be more species-specific than lethal toxicants, thus reducing the impact on non-target species. Fertility interventions could be a good strategy due to the high reproductive rates and short average life span of rodents. The greatest challenge for fertility interventions is delivery and disseminating of the agent across the entire population.

In most other animals, fertility intervention methods rely on intramuscular injection, which is not possible for free-ranging rodents. Many fertility interventions have been developed for pest control rather than eradication, though at sufficient volumes and density they could be used for eradication. As yet, there is no product of this type available for rodent eradication in Australia. The agent that presents the greatest option to date is the use of the toxic agent, 4-vinylcyclohexene diepoxide and triptolide. This is currently being commercialised under the name Contrapest.

Alternative toxicants, including fertility control, were considered by the LHIB in the Public Environment Report (LHIB, 2016). Fertility control using Contrapest was considered, although it is currently not registered in Australia. The Public Environment Report also noted other issues including method of distributing the chemical across the island. As such, the LHIB considered Contrapest not a viable option. Other toxicant/rodenticides were also considered based on their known efficacy in previous eradications, of these, brodifacoum was the preferred option (LHIB, 2016).

In general, the use of fertility interventions in rodent eradication programs is still under development and further research is required before they could be commercially feasible.

7 RECOMMENDATIONS FROM THE EXPERT PANEL

Recommendation 1
That the Lord Howe Island Board notes the Human Health Risk Assessment report and its advice that the proposed Rodent Eradication Program is not expected to result in adverse health effects for any individual due to exposure to brodifacoum.

Recommendation 2
Noting the considerable remaining community concern on Lord Howe Island, that the Minister request the Lord Howe Island Board to deliver:

4. a communication strategy for the period before and during the Rodent Eradication Program that clearly articulates the following:
   - the reason for the eradication and approach chosen
   - guidance to residents and visitors on actions that they should and could take during the Rodent Eradication Program to minimise exposure to brodifacoum
   - plans for follow-up measures that will be taken after the eradication program
5. a monitoring strategy to measure the outcomes and impacts of the Rodent Eradication Program, including for re-emergence of rodents, as well as triggers that would lead to further action
6. reports to the Minister following the Rodent Eradication Program on community and environmental outcomes, at designated timeframes, such as one month after the second bait distribution, one month after re-introduction of birds and cattle, and two years post Rodent Eradication Program.

REFERENCES

Aguirre-Muñoz, A, Croll, D.A, Donlan, C.J, Henry III, R.W, Hermosillo-Bueno, M. A, Howald, G.R, Keitt, B.S, Luna-Mendoza, L , Rodríguez-Malagón, M, Salas-Flores, L. M, Samaniego-Herrera, A, et al. (2008). High-impact conservation: invasive mammal eradications from the islands of western Mexico. *AMBIO: A Journal of the Human Environment, 37*(2), 101-107. doi: http://dx.doi.org/10.1579/0044-7447(2008)37[101:HCIMEF]2.0.CO;2

Appleton, D, Booker, H, Bullock, D.J, Cordrey, L, & Sampson, B. (2006). The Seabird Recovery Project: Lundy Island. *Atlantic Seabirds, 8*(1/2), 51-60.

APVMA. (2016a). Permits. Retrieved 17 January, 2016, from http://apvma.gov.au/node/611

APVMA. (2016b). Public Chemical Registration Information System Search. Retrieved 2 December, 2016, from https://portal.apvma.gov.au/pubcris

ArcGIS. (2016). World Topographic Map. Retrieved 10 December, 2016, from https://www.arcgis.com/home/webmap/viewer.html?useExisting=1&layers=30e5fe3149c34df1ba922e6f5bbf808f

Australian Government. (2016). *Poisons Standard November 2016 (SUSMP No. 15)*. Retrieved from https://www.legislation.gov.au/Details/F2016L01638.

Bassett, I.E, Cook, J, Buchanan, F, & Russell, J.C. (2016). Treasure Islands: biosecurity in the Hauraki Gulf Marine Park. *New Zealand Journal of Ecology 40(2)*.

Bell, E. (2011). Isles of Scilly Seabird Recovery Project: improving rodent control on uninhabited islands, assessment of the feasibility of rat removal across the Isles of Scilly archipelago and feasibility of rat removal from St Agnes and Gough, Prepared for: Isles of Scilly Seabird Recovery Project: Wildlife Management International Ltd.

Bell, E, Boyle, D, Floyd, K, Garner-Richards, P, Swann, B, Luxmoore, R, Patterson, A, & Thomas, R. (2011). *The ground-based eradication of Norway rats (Rattus norvegicus) from the Isle of Canna, Inner Hebrides, Scotland*. Paper presented at the Island Invasives: Eradication and Management: Proceedings of the International Conference on Island Invasives, Gland, Switzerland. http://www.issg.org/pdf/publications/island_invasives/islandinvasives.pdf

Brown, D. (2007). *A Feasibility Study for the Eradication of Rodents from Tristan da Cunha*. Report to the Royal Society for the Protection of Birds. Royal Society for the Protection of Birds, UK Retrieved from https://www.rspb.org.uk/Images/tristan%20da%20cunha%20rodent%20eradication_feasibiilty_tcm9-180955.pdf.

Campbell, K, Beek, J, Eason, C.T, Glen, A.S, Godwin, J, Gould, F, Holmes, N.D, Howald, G.R, Madden, F.M, Ponder, J.B, Threadgill, D.W, et al. (2015). The next generation of rodent eradications: Innovative technologies and tools to improve species specificity and increase their feasibility on islands. *Biological Conservation, 185*, 47-58. doi: http://dx.doi.org/10.1016/j.biocon.2014.10.016

Capizzi, D, Baccetti, N, & Sposimo, P. (2016). Fifteen Years of Rat Eradication on Italian Islands. In F. M. Angelici (Ed.), *Problematic Wildlife: A Cross-Disciplinary Approach* (pp. 205-227). Cham: Springer International Publishing.

Chevron Australia. (2014). Barrow Island Quarantine: Terrestrial and Marine Quarantine Management System.

Clout, M.N , & Russell, J.C. (2006). The eradication of mammals from New Zealand islands In F. Koike, M. N. Clout, M. Kawamichi, M. De Poorter & K. Iwatsuki (Eds.), *Assessment and Control of Biological Invasion Risks. Shoukadoh Book Sellers, Kyoto, Japan and the World Conservation Union (IUCN), Gland, Switzerland,* (pp. 127-141).

Critical Ecosystem Partnership Fund (CEPF). (2012). Pest Management Plan Critical Ecosystem Partnership Fund (CEPF).

Department of the Environment and Energy. (2016). *Threat abatement plan to reduce the impacts of exotic rodents on biodiversity on Australian offshore islands of less than 100 000 hectares - five yearly review*. Australian Government.

DIISE. (2015). The Database of Island Invasive Species Eradications. Retrieved 1 December, 2016, from http://diise.islandconservation.org

Ellis, C. (2013). Isles of Scilly rat eradication to 'save seabirds' begins. Retrieved 2 March, 2017, from http://www.bbc.com/news/uk-england-cornwall-24583514

Empson, R.A, & Miskelly, C.M. (1999). The risks, costs and benefits of using brodifacoum to eradicate rats from Kapiti Island, New Zealand. *New Zealand Journal of Ecology, 23*(2), 241-254.

enHealth. (2012). *Environmental Health Risk Assessment: Guidelines for assessing human health risks from environmental hazards*. Prepared by enHealth for the Australian Government Department of Health Retrieved from http://www.eh.org.au/documents/item/916.

Fisher, P, Griffiths, R, Speedy, C, & Broome, K. (2011). Environmental monitoring for brodifacoum residues after aerial application of baits for rodent eradication. In C. R. Veitch, M. N. Clout & D. R. Towns (Eds.), *Island invasives: eradication and management.* (pp. 300-304). Gland, Switzerland: IUCN.

Galapagos Conservancy. (2016). About Galapagos: The Islands. Retrieved 20 December, from http://www.galapagos.org/about_galapagos/about-galapagos/the-islands/

Gillespie Economics. (2016). Economic Evaluation of the Lord Howe Island Rodent Eradication Program.

Glen, A.S, Atkinson, R, Campbell, K.J, Hagen, E, Holmes, N.D, Keitt, B.S, Parkes, J.P, Saunders, A, Sawyer, J, & Torres, H. (2013). Eradicating multiple invasive species on inhabited islands: the next big step in island restoration? *Biological Invasions, 15*(12), 2589-2603. doi: 10.1007/s10530-013-0495-y

Government of South Georgia and the South Sandwich Islands. (2017). Eradication Projects/Rats, and Frequently Asked Questions. Retrieved 19 January, 2017, from http://www.gov.gs/environment/eradication-projects/eradication-projects-rats/, http://www.gov.gs/information/frequently-asked-questions/

Great Barrier Island Environmental News. (2016). Island Rat Eradications History and Development. Retrieved 19 December, 2016, from http://www.greatbarrierenvironews.nz/Newsletters/Issue7/Island%20Rat%20Eradications.htm

Greenslade, P, Burbridge, A.A, & Lynch, A.J.J. (2013). Keeping Australia's islands free of introduced rodents: the Barrow Island example. *Pacific Conservation Biology, 19*(3/4), 284-294.

Griffiths, R, Wegmann, A, Hanson, C, Keitt, B, Howald, G, Brown, D, Tershy, B, Pitt, W, Moran, M, Rex, K, White, S, et al. (2014). The Wake Island Rodent Eradication: Part Success, Part Failure, but Wholly Instructive. *USDA National Wildlife Research Center - Staff Publications, Paper 1774*, 101-111. http://digitalcommons.unl.edu/icwdm_usdanwrc/1774

Harper, G. A, & Carrion, V. (2011). *Introduced rodents in the Galápagos: colonisation, removal and the future. Island invasives: eradication and management.* Paper presented at the Island invasives: eradication and management. Gland, Switzerland, IUCN.

Hess, S.C, & Jacobi, J.D. (2011). *The history of mammal eradications in Hawai`i and the United States associated islands of the Central Pacific*. Paper presented at the Proceedings of the International Conference on Island Invasives, Tamaki Campus, University of Auckland, New Zealand. http://www.issg.org/pdf/publications/island_invasives/pdfHQprint/1Hess.pdf

Hill, M.J , Vel, T.M, Holm, K.J , Parr, S.J , & Shah, N.J (2002). Denis. In M. J. Hill (Ed.), *Biodiversity Surveys and Conservation Potential of Inner Seyschells Islands, Atoll Research Bulletin, No. 495*

Holmes, N. D, Griffiths, R, Pott, M, Alifano, A, Will, D, Wegmann, A.S, & Russell, J.C. (2015). Factors associated with rodent eradication failure. *Biological Conservation, 185*, 8-16. doi: http://dx.doi.org/10.1016/j.biocon.2014.12.018.

Howald, G, Samaniego, A, Buckelew, S, McClelland, P, Keitt, B, Wegmann, A, Pitt, W.C, Vice, D.S, Campbel, I E, Swift, K, & Barclay, S. (2004). Palmyra Atoll rat Eradication Assessment Trip Report. Retrieved 10 August, 2016, from http://rce.pacificinvasivesinitiative.org/tools/Further_Information/2.%20Feasbility%20Study/Palmyra%20Atoll%20Rat%20Eradication%20Feasibility%20FINAL.pdf

Howald, G., Donlan, C. J., Galvan, J.P., Russell, J.C., Parkes, J., Samaniego, A., Wang, Y., Veitch, D., Genovesi, P., Pascal, M., Saunders, A., et al. (2007). Invasive Rodent Eradication on Islands. *Conservation Biology, 21*(5), 1258-1268. doi: 10.1111/j.1523-1739.2007.00755.x

Island Conservation. (2013). *Floreana Island Ecological Restoration: Rodent and Cat Eradication Feasibility Analysis version 6.0. Island Conservation*. Retrieved from https://www.cbd.int/doc/lifeweb/Ecuador/images/FeasibilityAnalysis.pdf.

Island Conservation. (2017). Protect Palmyra: Project Updates. Retrieved 19 January, 2017, from http://www.protectpalmyra.org/blog/

Keitt, B, Griffiths, R, Boudjelas, S, Broome, K, Cranwell, S, Millett, J, Pitt, W, & Samaniego-Herrera, A. (2015). Best practice guidelines for rat eradication on tropical islands. *Biological Conservation, 185*, 17-26. doi: http://dx.doi.org/10.1016/j.biocon.2014.10.014

Latofski-Robles, M, Aguirre-Muñoz, A, Méndez-Sánchez, F, Reyes-Hernández, H, & Schlüter, S. (2014). Prioritizing Restoration Actions for the Islands of Mexico. *Monographs of the Western North American Naturalist, 7*(1), 435-441. doi: 10.3398/042.007.0133

LHIB. (2016). *Lord Howe Island Rodent Eradication Project: Public Environment Report EPBC 2016/7703*. Prepared by Lord Howe Island Board Retrieved from http://www.lhib.nsw.gov.au/sites/lordhowe/files/public/images/documents/lhib/Environment/Rodent%20Eradication/LHI%20REP%20Final%20Public%20Environment%20Report_21Dec2016.pdf.

Lohr, C, Van Dongen, R, Huntley, B, Gibson, L, & Morris, K. (2014). Remotely Monitoring Change in Vegetation Cover on the Montebello Islands, Western Australia, in Response to Introduced Rodent Eradication. *PLoS ONE, 9*(12), e114095. doi: 10.1371/journal.pone.0114095

MacKay, J.W.B, & Russell, J.C. (2005). Ship rat Rattus rattus eradication by trapping and poison-baiting on Goat Island, New Zealand. *Conservation Evidence, 2*, 142-144.

MacKay, J.W.B, Russell, J.C, & Murphy, E.C. (2007). *Eradicating house mice from islands: Successes, failures and the way forward*. Paper presented at the Managing Vertebrate Invasive Species, Collorado.

Matthews, E. (2007). Community-based and collaborative management of coral reefs and coastal resources in Palau.

McClelland, P. (2011). *Campbell Island – pushing the boundaries of rat eradications*. Paper presented at the Island Invasives: Eradication and Management. Proceedings of the International Conference on Island Invasives, Gland, Switzerland. http://www.issg.org/pdf/publications/island_invasives/islandinvasives.pdf

McFadden, I, & Greene, T. (1994). *Using Brodifacoum to Eradicate Kiore (Rattus Exulans) from Burgess Island and the Knights Group of the Mokohinau Islands*. Wellington, New Zealand: Head Office, Department of Conservation Retrieved from http://www.doc.govt.nz/Documents/science-and-technical/sr70.pdf.

Merton, D, Climo, G, Laboudallon, V, Robert, S, & Mander, C. (2002). Alien mammal eradication and quarantine on inhabited islands in the Seychelles *Proceedings of the International Conference on Eradication of Island Invasives (Occasional Paper of the IUCN Species Survival Commission No. 27. Veitch, C. R. and Clout, M.N., eds. 2002.).* (pp. 182-198).

National Statistics Institute Italy. (2016). Census 2001. from http://dawinci.istat.it/MD/dawinciMD.jsp?a1=W0I040WI0&a2=mG0Y8048f8&n=1UH90007SN5&v=1UH07B07SN50000
Nicholls, H. (2013). Invasive species: The 18-km2 rat trap. *Nature, 497*, 306-308.
Northwestern Hawaii Islands Multi-agency Education Project, Laboratory for Interactive Learning Technologies. (2002). Community on Midway. Retrieved 2 March, 2017, from http://www.hawaiianatolls.org/video/nowramp020924.php
NSW EPA. (2016). Managing pesticides in NSW. from http://www.epa.nsw.gov.au/pesticides/pestmmngngNSW.htm
OCSE. (2016). Independent Human Health Risk Assessment for the Lord Howe Island Rodent Eradication Program. Retrieved 24 November, 216, from http://www.chiefscientist.nsw.gov.au/reports/independent-review-of-the-lord-howe-island-rodent-eradication-project
Ogden, J, & Gilbert, J. (2011). *Running the gauntlet: advocating rat and feral cat eradication on an inhabited island – Great Barrier Island, New Zealand*. Paper presented at the Island Invasives: Eradication and Management. Proceedings of the International Conference on Island Invasives, Gland, Switzerland. http://www.issg.org/pdf/publications/island_invasives/islandinvasives.pdf
Ogden, J., & Gilbert, J. (2009). Prospects for the eradication of rats from a large inhabited island: community based ecosystem studies on Great Barrier Island, New Zealand. *Biological Invasions, 11*(7), 1705-1717. doi: 10.1007/s10530-008-9398-8
Oppel, S, Beaven, B. M, Bolton, M, Vickery, J, & Bodey, T. W. (2011). Eradication of Invasive Mammals on Islands Inhabited by Humans and Domestic Animals. *Conservation Biology, 25*(2), 232-240. doi: 10.1111/j.1523-1739.2010.01601.x
Pacific Invasives Initiative. (2016). PII Resource Kit for Rodent and Cat Eradication. Retrieved 9 January, 2017, from http://www.pacificinvasivesinitiative.org/
Palau Conservation. (2011). Kayangel Rodent Eradication Operational Plan.
Parks and Wildlife Services Tasmania. (2009). *Macquarie Island Pest Eradication Project. Part C – Environmental Impact Statement*. Hobart Tasmania: Department of Primary Industries, Parks, Water and Environment Retrieved from http://www.parks.tas.gov.au/file.aspx?id=16721.
Parks and Wildlife Services Tasmania. (2015). Macquarie Island Pest Eradication Project. Retrieved 2 December, 2016, from http://www.parks.tas.gov.au/index.aspx?base=12997
Plant Conservation Action group. (2009). Review of Invasive Alien Species (IAS) Control and Eradication Programmes in Seychelles. Retrieved 24 August, 2016, from http://www.pcaseychelles.org/uploads/1/2/3/6/12369400/seychelles_ias_control-erad_review_pca_report___annexes.pdf
Predator Free Rakiura (PFR) Governance Group. (2015a). Predator Free Rakiura Halfmoon Bay (HMB) Project—summary of options for predator removal. Discussion document prepared by the PFR Governance Group, c/o Southland District Council, Invercargill. 5 p. Retrieved 29 September, 2016, from http://3szu394er40s2g7qle33co16.wpengine.netdna-cdn.com/wp-content/uploads/2015/09/HMB-Project-summary.pdf
Predator Free Rakiura (PFR) Governance Group. (2015b). Predator Free Rakiura Halfmoon Bay Project—methods for predator removal. Discussion document prepared by Eco South for the Predator Free Rakiura (PFR) Governance Group, c/o Southland District Council, Invercargill. 56 p. from http://3szu394er40s2g7qle33co16.wpengine.netdna-cdn.com/wp-content/uploads/2015/09/HMB-Project-report-1.pdf
Priddel, D, Carlile, N, Wilkinson, I, & Wheeler, R. (2011). *Eradication of exotic mammals from offshore islands in New South Wales, Australia*. Paper presented at the Island Invasives: Eradication and Management: Proceedings of the International Conference on Island Invasives, Gland, Switzerland. http://www.issg.org/pdf/publications/island_invasives/islandinvasives.pdf

Rodríguez, C, Torres, R, & Drummond, H. (2006). Eradicating introduced mammals from a forested tropical island. *Biological Conservation, 130*(1), 98-105. doi: http://dx.doi.org/10.1016/j.biocon.2005.12.005

Russell, J.C, Towns, D.R, & Clout, M.N. (2008). *Review of rat invasion biology : implications for island biosecurity*. Wellington, N.Z: Science & Technical Pub., Dept. of Conservation.

Samaniego-Herrera, A, Aguirre-Muñoz, A , Rodríguez-Malagón, M , González-Gómez, R , Torres-García, F, Méndez-Sánchez, F, Félix-Lizárraga, M, & Latofski-Robles, M. (2011). *Rodent eradications on Mexican islands: advances and challenges*. Paper presented at the Island Invasives: Eradication and Management. Proceedings of the International Conference on Island Invasives, Gland, Switzerland. http://www.issg.org/pdf/publications/island_invasives/islandinvasives.pdf

Saunders, A, Blaffart, H, Morley, C, Kuruyawa, J, Masibalavu, V., & Seniloli, E. (2007). *A "Community" Approach to Invasive Species Management: Some Pacific Case Studies*. Paper presented at the Managing vertebrate invasive species: proceedings of an international symposium, Fort Collins, Colorado, USA. http://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1044&context=nwrcinvasive

Saunders, A, Glen, A, Campbell, K, Atkinson, R, Sawyer, J, Hagen, E, & Torres, H. (2011). Feasibility of managing invasive species in the Juan Fernandez Archipelago, Chile: Report to the Corporaction Nacional Forestal and the Municipalidad de Juan Fernandez. Landcare Research.

Senestech. (2016). Rodent control: Our product. Retrieved 31 January, 2016, from http://senestech.com/rodent-control-our-product/

Seychelles National Bureau of Statistics. (2002). *National Population & Housing Census*

Sinclair, L, McCartney, J, Godfrey, J, Pledger, S, Wakelin, M, & Sherley, G. (2005). How did invertebrates respond to eradication of rats from Kapiti Island, New Zealand? *New Zealand Journal of Zoology, 32*(4), 293-315. doi: 10.1080/03014223.2005.9518421

South Georgia Heritage Trust. (2010). *Environmental Impact Assessment for the eradication of rodents from the island of South Georgia*. Prepared by South Georgia Heritage Trust Retrieved from http://www.sght.org/sites/default/files/SGHR%20project%20EIA%2011%20Dec%202010%20MASTER.pdf.

Swegen, A, Zamira, G, & Aitken, R.J. (2017). *Fertility intervention and toxicant technologies for the eradication of rodents on Lord Howe Island*. Priority Research Centre in Reproductive Science, School of Environmental and Life Sciences, Faculty of Science and Information Technology, the University of Newcastle

Taylor, M, Sandy, N, & Raphael, B. (2013). Background Paper on Community Concerns in relation to Coal Seam Gas. http://www.chiefscientist.nsw.gov.au/__data/assets/pdf_file/0010/31789/Community-Concerns-in-relation-to-Coal-Seam-Gas_Taylor,-Sandy-and-Raphael_UWS.pdf

The Motutapu Restoration Trust. (2016). Motutapu. from http://www.motutapu.org.nz/index.php

Thorsen, M, Shorten, R, Lucking, R, & Lucking, V. (2000). Norway rats (*Rattus norvegicus*) on Frégate Island, Seychelles: the invasion; subsequent eradication attempts and implications for the island's fauna. *Biological Conservation, 96*(2), 133-138. doi: http://dx.doi.org/10.1016/S0006-3207(00)00059-8

U.S. Fish & Wildlife Service. (2013). *South Farallon Islands Invasive House Mouse Eradication Project; Farallon National Wildlife Refuge, California; Revised Draft Environmental Impact Statement*. Prepared by United States Fish and Wildlife Service: Retrieved from https://www.fws.gov/uploadedFiles/Farallon_House_Mouse_Eradication_Revised_DEIS_compressed.pdf.

U.S. Fish & Wildlife Service. (2017). Midway Atoll National Wildlife Refuge and Battle of Midway National Memorial: Refuge Reports. Retrieved 19 January, 2017, from

https://www.fws.gov/refuge/Midway_Atoll/Resource_Management/Refuge_Report.html
UNEP. (2006). Islands: Island Directory. Retrieved 10 December, 2016, from http://islands.unep.ch/Iindex.htm
US EPA. (2011). *Exposure Factors Handbook 2011 Edition (Final)*. (EPA/600/R-09/052F). Washington, DC: Prepared by the US Environmental Protection Agency.
US EPA. (2016a). Human Health Risk Assessment. Retrieved 9 December, 2016, from https://www.epa.gov/risk/human-health-risk-assessment
US EPA. (2016b). Restrictions on Rodenticide Products. Retrieved 10 January, 2016, from https://www.epa.gov/rodenticides/restrictions-rodenticide-products
US EPA. (2016c). Safely Use Rodent Bait Products. Retrieved 10 January, 2016, from https://www.epa.gov/rodenticides/safely-use-rodent-bait-products
Varnham, K, Glass, T, & Stringer, C. (2011). *Involving the community in rodent eradication on Tristan da Cunha.* Paper presented at the Island invasives: eradication and management. IUCN, Gland, Switzerland.
WHO. (2016). Public Health Services. Retrieved 13 December, 2016, from http://www.euro.who.int/en/health-topics/Health-systems/public-health-services
Williams, G. J., Smith, J. E., Conklin, E. J., Gove, J. M., Sala, E., & Sandin, S. A. . (2013). Benthic communities at two remote Pacific coral reefs: effects of reef habitat, depth, and wave energy gradients on spatial patterns. *PeerJ, 1*(e81).
Witmer, G.W, & Hall, P. (2011). *Attempting to eradicate invasive Gambian giant pouched rats (Cricetomys gambianus) in the United States: lessons learned*. Paper presented at the Island Invasives: Eradication and Management: Proceedings of the International Conference on Island Invasives, Gland, Switzerland. http://www.issg.org/pdf/publications/island_invasives/islandinvasives.pdf
Wolfaardt, A.C, Glass, J, & Glass, T. (2009). Tristan da Cunha implementation plan for the Agreement on the Conservation of Albatrosses and Petrels (ACAP): Review of current work and a prioritised work programme for the future. Tristan da Cunha Government.

Acronyms

APVMA	Australian Pesticides and Veterinary Medicines Authority
CSE	NSW Chief Scientist & Engineer
DIISE	Database of Islands and Invasive Species Eradications
FGARs	First-Generation Anticoagulant Rodenticides
HHRA	Human Health Risk Assessment
LHI	Lord Howe Island
LHIB	Lord Howe Island Board
NOEL	No Observed Effect Level
OCSE	Office of the NSW Chief Scientist & Engineer
ppm	parts per million
REP	Rodent Eradication Program
SGARs	Second-Generation Anticoagulant Rodenticides
US EPA	US Environment Protection Agency
WHO	World Health Organization

APPENDICES

APPENDIX 1 LHI REP HHRA EXPERT PANEL TERMS OF REFERENCE AND MEMBERSHIP

Terms of Reference

The Lorde Howe Island Board (Board) is working to implement the Lord Howe Island Rodent Eradication Plan. In developing the Plan, the Board has committed to commissioning an independent Human Health Risk Assessment (HHRA) for the Plan, and to have the HHRA independently reviewed.

To assist in the process of developing the Independent HHRA, the NSW Chief Scientist & Engineer is requested to:

1. Provide advice to the Board on processes for commissioning the HHRA including identification of suitable experts and scope of the request for proposal
2. Convene an Expert Panel to review proposals to undertake the HHRA and select a preferred candidate; review project plans and methodologies; and review draft and final reports of the HHRA as required
3. Provide advice to the Minister for the Environment on the HHRA
4. Respond to media enquires as they relate to the Terms of Reference for the Expert Panel

Chair and membership

The Expert Panel will comprise:

- Professor Mary O'Kane, NSW Chief Scientist & Engineer (Chair)
- Dr Chris Armstrong, Director, Office of the Chief Scientist & Engineer (Deputy Chair)
- Two independent experts
    - Professor Brian Priestly, Director of the Australian Centre for Human Health Risk Assessment, Monash University School of Public Health & Preventive Medicine
    - Emeritus Professor Stephen University of Sydney

Secretariat

Secretariat support to the Expert Panel and the Chair will be provided by the Office of the Chief Scientist & Engineer

APPENDIX 2 RAMBOLL ENVIRON AUSTRALIA PTY. LTD. REPORT

Intended for
The Office of the Chief Scientist & Engineer

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HUMAN HEALTH RISK ASSESSMENT

PROPOSED LORD HOWE ISLAND RODENT ERADICATION PROGRAM

RAMBOLL ENVIRON

HUMAN HEALTH RISK ASSESSMENT PROPOSED LORD HOWE ISLAND RODENT ERADICATION PROGRAM

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ABBREVIATIONS

µg	Microgram abbreviations
µS	Micro Siemens
ADI	Acceptable daily intake
AEL	Acceptable Exposure Level
AF	Assessment Factors
APVMA	Australian Pesticides and Veterinary Medicines Authority
BCF	Bioaccumulation Factor
bgl	Below ground level
BOM	Bureau of Meteorology (Australian Government)
BPC	Biocidal Products Committee
cm	Centimetres
CSM	Conceptual Site Model
DAF	Dilution Attenuation Factor
DNA	Deoxyribonucleic Acid
EPBC	Environment Protection and Biodiversity Conservation
EPC	Exposure Point Concentration
GHS	Global Harmonisation System
GLP	Good Laboratory Practice
GRP	Gla-rich protein
GPS	Global Positioning System
ha	Hectares
HHRA	Human Health Risk Assessment
HI	Hazard Index
HQs	Hazard Quotients
IUCN	International Union for Conservation of Nature
KCT	Kaolin-cephalin time
kg	Kilograms
km	Kilometres
Kow	Octanol-water partition coefficient
LOEL	Lowest observed effect level
LHI	Lord Howe Island
LHIB	Lord Howe Island Board
m	Metres
mg	Milligram
MGP	Matrix Gla protein
mm	Millimetre

MPN	Most Probable Number
NGWA	National Groundwater Association
NOEL	No-observed effect level
NTU	Nephelometric Turbidity Units
OCSE	Office of the Chief Scientist & Engineer
OECD	Organisation for Economic Co-operation and Development
PIC	Poisons Information Centre
ppm	Parts per million
PT	Prothrombin time
RAC	Risk Assessment Committee
REP	Rodent Eradication Program
RfD	Systemic reference dose
SPR	Source-Pathway-Receptor
TDS	Total Dissolved Solids
TRV	Toxicity reference value
UCHA	European Chemicals Agency
UNESCO	United Nations Educational, Scientific and Cultural Organization
UV	Ultra Violet
VKOR	Vitamin K epoxide reductase
WHO	World Health Organisation

EXECUTIVE SUMMARY

Lord Howe Island (LHI) is located in the Tasman Sea, approximately 600 km off the Australian coast from Port Macquarie in NSW. LHI is a UNESCO World Heritage Site and a NSW State Marine Park, with much of the island's mountainous forest having a Permanent Park Preserve status. The main inhabited island is approximately 10 km long and between 2 km and 0.3 km wide, with an overall area of 14.55 km^2. There are approximately 350 island residents and the island is a tourist destination, with up to 400 visitors permitted on the island at a time.

Rodents that have colonized the island group, namely the ship rat (*Rattus rattus*) and the house mouse (*Mus musculus*) have resulted in various adverse impacts to the flora and fauna and economy and currently jeopardize the island group's status as a World Heritage Site. In addition the residents and island's administrative agency have to aggressively manage rodent populations in the settlement area of the island to minimize human encounters with rodents and damage to agriculture and gardens. Commercially available rodenticides are currently used throughout the settlement area and by individual residents around their property for control of rodents.

The Lord Howe Island Board (LHIB) administers the island and has proposed carrying out a one-time rodent eradication programme (REP) intended to permanently eliminate rat and mouse populations. These types of intensive programs have successfully eradicated rodents on other relatively small islands and the LHIB has developed the programme based on documented successes elsewhere. The proposed REP includes using bait pellets containing the anticoagulant rodenticide brodifacoum ("bro-diff-a-coom"), which has been the most effectively used agent in successful eradications. The pellets would be distributed throughout the entire area of the main island and nearby islets using several distribution methods.

The proposed REP has been the subject of extensive study and discussion by various stakeholders, including island residents, and a variety of questions and concerns have been posed. In 2010, a Human Health Risk Assessment (HHRA) was undertaken by a consultant for the LHIB. Additional studies and regulatory submittals have also been undertaken and, in light of the complexity and desire to have independent third-party review, the LHIB has requested an evaluation of the human health issues related to the REP by the Office of the Chief Scientist & Engineer (OCSE). OCSE commissioned Ramboll Environ Australia Pty Ltd (Ramboll Environ) to perform an updated HHRA for the proposed REP.

Since the prior HHRA was initiated, international agencies that evaluate the type of potential effects from chemicals that should be considered in risk assessment, particularly the European Union and European Chemical Agency, have updated their characterisations and recommendations regarding brodifacoum. Most significantly, teratogenic effects (disruption of the normal development of bone structures during foetal growth) documented in cases where pregnant patients were taking a compound similar to brodifacoum (i.e., warfarin) were specified to be the basis for determining the most protective exposure levels to employ in assessing brodifacoum. While neither animal testing nor case reports of human poisoning incidents have shown this type of foetal effect from brodifacoum, it is common and appropriate to consider effects from related chemicals where there is sufficient similarity and mechanisms of action between the chemicals. The current HHRA expands the types of exposures considered by incorporating information from the community and LHIB that has become available since the initial risk assessment and uses the updated recommendations regarding exposure levels that account for potential developmental concerns.

The human receptors of concern included for quantitative risk estimation in this HHRA are a toddler child, a young school child (approximately 8-11 years old), an adult woman that could potentially be pregnant, and a general adult that might be out of doors extensively during the REP. For chemicals that have non-cancer effects, exposure scenarios involving children are typically more protective than adult scenarios due to the low body weight of children. The potentially pregnant adult scenario was included specifically to match up to the updated recommendation that potential developmental effects be considered in brodifacoum risk assessment. The typical adult scenario was included to address specifically outdoor exposure such as might be undertaken by residents or visitors trekking in the park preserve extensively during the REP.

The pathways of exposure considered for these scenarios include:

- Incidental ingestion and dermal contact with soil beneath/adjacent to a degraded pellet
- Outdoor inhalation of dust derived from pellets during aerial and hand broadcasting distribution
- Ingestion of tank water/groundwater as drinking water
- Direct contact and incidental ingestion of surface water
- Direct contact and incidental ingestion of creek sediment
- Ingestion of locally caught seafood
- Ingestion of locally grown vegetables and fruit
- Direct ingestion of Pestoff 20R pellets

The results of the quantitative risk estimation demonstrate that for all of the receptor scenarios, the expected exposures would be below the corresponding dose level derived to be safe for sensitive subpopulations and accounting for the sensitive effects of brodifacoum. This outcome supports a conclusion that adverse health effects would not be expected from the projected brodifacoum exposures related to the REP. Although not quantitatively assessed in the HHRA, consideration was also given for the potential health effects to the elderly population on LHI and patients taking warfarin for therapeutic purposes.

The pathways estimated to contribute most to the projected exposures included ingestion of soil (assumed to be from directly beneath bait pellets), ingestion of tank water as drinking water (driven by the assumed landing of bait pellets on roofs during aerial distribution), dermal contact with sediment (assumed to be directly beneath bait pellets landing in streams or on the beach), and inhalation of airborne dust during the aerial distribution operations. While there were no indications that exposure would exceed safe levels, this information may be useful for planning management and oversight of the REP.

In summary, a comprehensive evaluation of the environmental releases projected from the REP did not identify exposures expected to lead to adverse health effects. In addition, a supplemental evaluation to consider accidental acute ingestion of bait pellets by a child was included to respond to community concerns about such incidents. This evaluation demonstrates that incidental exploratory contact such as handling or mouthing/ingesting one or a few pellets would not be expected to result in observable anticoagulant effects and provides information that stakeholders can use in judging the margin of safety for children. The overall conclusion from this risk assessment is that estimates of exposure from all the potential sources associated with the REP are below those likely to result in adverse health effects in any individuals.

1. INTRODUCTION

The Office of the Chief Scientist & Engineer (OCSE), commissioned Ramboll Environ Australia Pty Ltd (Ramboll Environ) to perform a human health risk assessment (HHRA) for the proposed Lord Howe Island Rodent Eradication Program.

This HHRA is undertaken in accordance with the Australian guideline for conducting human health risk assessment as outlined in *enHealth (2012) Environmental Health Risk Assessment, Guidelines for assessing human health risks from environmental hazards*. *Commonwealth of Australia* modified to address factors related to the circumstances of a proposed future use of a specific pesticide product.

1.1 Background

Lord Howe Island (LHI) is located in the Tasman Sea, approximately 600 km off the Australian coast from Port Macquarie in NSW (**Figure 1, Appendix A**). LHI is a UNESCO World Heritage Site and a NSW State Marine Park, with much of the island's mountainous forest having a Permanent Park Preserve status. The Lord Howe Island Board (LHIB) is directly responsible to the NSW Minister for Environment, and comprises four Islanders elected by the local community and three members appointed by the Minister. The LHIB is charged with the care, control and management of the island's natural values and the affairs and trade of LHI; and is also responsible for the care and welfare of the approximately 350 island residents.

The LHIB has identified a rodent issue on Lord Howe Island and its associated islands and rocky islets (the Lord Howe Island Group (LHIG)), excluding Balls Pyramid; namely the ship rat (*Rattus rattus*) and the house mouse (*Mus musculus*). The rodents are reported to be having a direct impact to the ecology of LHI via predation on some of the island's protected birds (e.g. Lord Howe Island woodhens (*Gallirallus sylvestris*)), a bat species, reptiles, fungi, invertebrates, and eggs. Indirectly, rats are impacting LHI's ecology via the consumption of vast quantities of seeds, flowers and fruits; thus reducing food supplies, increasing the competition for food, and hindering the regeneration of plants on the island. Rats are also impacting the island's nutrient cycle as the predation of seabirds results in a reduction in the production of nutrients from guano, regurgitations and failed eggs. As a result, rats have been implicated to the extinction of five endemic bird taxa, and at least 13 species of endemic invertebrates (DEWHA, 2009). They are also a recognised threat to at least 13 bird species, two reptiles, 51 plant species, 12 vegetation communities, and three species of threatened invertebrates (DECC, 2007).

A range of rodent poisons (e.g. barium chloride, warfarin) have historically been used to manage populations and the mice on LHI now demonstrate resistance to warfarin. Resistance has been observed as a genetic adaptation in long-term pest control and cross-resistance between warfarin and other first generation anticoagulants has been reported (Buckle *et al*, 1994). Cross-resistance between warfarin and some second-generation anticoagulants such as bromadiolone and difenacoum anticoagulants, and to a lesser extent brodifacoum, has also been reported (Buckle *et al*, 1994; Buckle and Smith, 2015). Research conducted in the United Kingdom and Germany has identified which part of the genetic code of rats and mice carried the DNA sequence, or gene, which alters when rodents become resistant to anticoagulants (RRAG, 2010; Buckle and Prescott, 2012). To address this issue, the LHIB is proposing a one-off eradication program via the distribution of a cereal-based rodent bait pellet (Pestoff 20R) containing the second generation anticoagulant brodifacoum at a concentration of 20 mg/kg (equivalent to parts-per-million [ppm]). The proposed method of distribution will be from helicopters using an under-slung bait spreader bucket in the uninhabited parts of the island (the majority of the LHIG), and by a combination of hand broadcasting and the placement of bait in trays and bait stations in the remaining portions of the settlement area. Bait stations will also be used particularly around residences, businesses, and pens for any remaining livestock. While rodent management is currently undertaken using bait stations, this method alone is not anticipated to be feasible for eradication given the size and rugged terrain of the LHIG.

The LHIB has made an application to the Australian Pesticides and Veterinary Medicines Authority (APVMA) to use brodifacoum as part of the eradication program (LHIB, 2016b). The APVMA application reported that a maximum of 42 tonnes of Pestoff 20R (containing a maximum total of 840g of brodifacoum) will be used over two application periods, with 14-21 days in between each application, resulting in a total treatment rate of 20 kg/ha averaged over the island (LHIB, 2016b). It is understood that the eradication program is targeted for winter of 2017 (June to August, when rodents are most vulnerable due to food shortage), but a three year approval period is being sought to undertake the program in case of unforeseen delays.

The proposed eradication program has been the subject of community discussion, and a number of planning documents and reports over a number of years. Amongst concerns to local wildlife (including threatened and vulnerable species), cattle, marine ecology and pets, are impacts to the health of island residents due to potential exposure to the Pestoff 20R pellets containing brodifacoum. In 2010, a Human Health Risk Assessment (HHRA) was completed by Toxikos to evaluate human health concerns; however some concerns have continued to be expressed about potential human health impacts of the eradication program, including through aerial broadcast of the pellets.

Consequently, to address these human health concerns and update the HHRA with current information on brodifacoum, the LHIB is commissioning a further HHRA with independent oversight of the process through an Expert Panel chaired by Professor Mary O'Kane (NSW Chief Scientist & Engineer), with members Professor Brian Priestly (Monash University), Professor Steven Leeder (Sydney University) and Dr Chris Armstrong (Office of Chief Scientist & Engineer (OCSE)).

1.1.1 Current Rodent Control Programs and Practices

Since the 1920s, various methods of rodent control have been implemented on LHI including a bounty on rat tails, hunting with dogs, introduction of cats and owls and the use of poisons including barium chloride, diphacinone and warfarin.

A limited rodent control program is currently being implemented by the LHIB using approximately 1400 bait stations across the island containing the active ingredient coumatetryl in the product Racumin or Ratex (refer to **Photograph 1, Appendix B**). Coumatetryl is a first generation anticoagulant that has a similar mode of action to warfarin (i.e. inhibiting the synthesis of vitamin K-dependent clotting factors). These bait stations were observed by Ramboll Environ during a site visit conducted between 8 and 11 November 2016 (refer to **Section 1.2**). The bait stations comprise plastic tubing in a 'T' or 'L' configurations (refer to **Photographs 5** and **6, Appendix B)** and are placed throughout the island's settlement area and in some sections of the Permanent Park Preserve; comprising approximately 10% of the island's surface area. It is understood that the LHIB have an APVMA permit to apply the bait in stations with 200g of bait which is replenished five times per annum (approximately every 10 weeks). Coumatetryl is also supplied by the LHIB to residents who wish to use it on their properties. In 2015, the LHIB purchased a total of 2880 kg of Ratex grain containing coumatetryl for use in the rodent control program; and between January and July 2015 the LHIB used and provided to residents approximately 700 kg of Ratex grain for rodent control on the island.

Coumatetryl is currently used largely due to the LHIB being unable to source commercial quantities of warfarin as a consequence of rodents being largely resistant to it on the mainland. Furthermore, coumatetryl has a comparatively lower impact on non-target species on the island in comparison to warfarin.

It is understood that some residents currently use brodifacoum based rodenticides such as Talon™ and Tomcat™ (refer to **Photograph 3, Appendix B**), sourced locally on the island and from the mainland. Talon contains brodifacoum at a concentration of 50 mg/kg, and the trays containing the Talon pellets are placed on resident's properties and inside dwellings. An estimated 400 kg of brodifacoum-based rodenticides are used by residents annually which is equivalent to an annual environmental dispersion of 20 g of brodifacoum.

It is our understanding that no incidents of adverse effects to residents from these products have been reported to the hospital on the island, Following an information request to the NSW Poisons Information Centre (PIC), it is understood that children aged one year and younger represented the largest age group to have reported cases of definite exposures to brodifacoum, with ingestion being the most common route of exposure followed by dermal exposure. Children aged between two and three years old were reported as the next largest exposed group while no definite reported exposures were reported for school aged children aged between 8 and 11 years old. Adults aged 18 years and older accounted for 9% of all reported definite exposure to brodifacoum. This information was recorded for all of NSW, and specific information relating brodifacoum exposures to residents and visitors to LHI was unavailable.

1.1.2 Proposed Rodent Eradication Program

The proposed REP aims to eradicate all ship rats and house mice from the LHI Group while minimising adverse impacts on the environment, non-target species, humans, livestock and pets. The aim is to achieve the REP in a single approximately 100-day operation via the distribution of a cereal-based pellet (Pestoff 20R) containing 20 mg/kg of brodifacoum across the LHI Group (excluding Balls Pyramid). This will include two bait distribution events separated by approximately 14-21 days each covering most of the target area and ongoing use of bait stations throughout the operation period. Baits distributed in the open are expected to weather and degrade in the environment as additional management steps such as rodent carcass collection (in accessible areas) are completed during the remainder of the operation period. Also, certain livestock and trapped bird populations will be isolated from bait stations and rodent carcasses during this period. The REP is targeted for winter of 2017 (June to November) when the availability of natural food for rodents is low, rodent breeding is greatly reduced and when most non-target seabirds are absent. To allow for operational flexibility and to account for unforeseen delays, the LHIB has sought approval for a three year period in which to carry out the REP, with the intention of carrying out the REP once only during the three year period. The bait will be distributed at a total nominal rate of 20 kg of bait (or 0.4 g of brodifacoum) per hectare requiring a total of 42 tonnes of bait (containing a maximum total of 840 g of brodifacoum) to cover the total island group surface area of 2100 ha.

Several methods for distributing the Pestoff 20R pellets across LHI are proposed as part of the REP including aerial broadcasting, hand broadcasting and bait stations. The proposal is for the aerial and hand baiting approaches to be carried out over two applications so that juveniles that emerge from their den after the first application and animals that fail to consume a lethal dose have subsequent access to a renewed reservoir of baits. These methods are described in detail below.

- *Aerial broadcasting*: aerial baiting will be conducted throughout the LHI Permanent Park Preserve and other areas of the main island excluding the settlement area, some sections of the coastline (e.g. Lagoon Foreshore) and identified buffer zones. Buffer zones are defined as an area in which aerial baiting cannot take place, and is a distance of 30 m to buildings, or 150 m depending on the property holder's preference. 10 mm diameter baits (approximately 2 g each) will be broadcast at a density of 12 kg/ha (one bait every two square metres) for the first application and 8 kg/ha for the second application. The bait will be dispersed using a purpose built spreader bucket slung below a helicopter. A rotating disc throws the bait 360° consistently to 35 m (noting that outliers can reach up to 45 m) enabling a swathe of up to 70 m to be baited in a single pass. A 50% overlap of each swathe will be used to ensure that there are no gaps in the distribution of baits and this is accounted for in the calculation of the application density (e.g., 1 bait per 2 m^2) identified above. Each bait application will take approximately two days to complete depending on the weather. In order to achieve the required baiting density on the cliffs and steep slopes (particularly around Mount Gower and Mount Lidgbird) several horizontal flight lines will be flown at approximately 50 m vertical spacing along these areas to ensure adequate bait coverage. Baiting around the coast line will occur above the mean high water mark to minimise bait entry into the marine environment. A deflector arm will be attached to the spreader bucket to restrict the arc of the swathe to 180º and will be used particularly when baiting the edge of buffer zones and when baiting coastal areas.

- *Hand broadcast*: hand broadcasting of bait will be conducted concurrently with aerial baiting throughout the settlement area where agreed by residents and in buffer and exclusion zones such as The Lagoon foreshore and Ned's Beach. Hand broadcasting will be conducted using teams of trained personnel in working lines across a prescribed area via the use of hand operated pellet distributers. All personnel will carry a GPS unit capable of continuously tracking their path, and computer-generated plots of their path will be used to check for baiting coverage. In the settlement area, either 10 mm diameter (2 g each) or 5.5 mm diameter Pestoff 20R baits (0.6 g each) will be hand-broadcasted at a density of 12 kg/ha for the first application of bait and at 8 kg/ha for the second application (one pellet every 2 square metres for 10 mm pellets or one pellet every half square metre for 5.5 mm pellets). No bait will be hand-broadcast directly in or under buildings where it would not be subject to weathering.

- *Bait Stations and Trays*: commercially available or specifically designed bait stations will be used where aerial or hand broadcasting are not undertaken. An example of a bait station proposed to be used is shown in **Photograph 4, Appendix B**. To the maximum extent possible, beef cattle, chickens and goats will be removed from the island prior to the REP and bait stations will be placed within all areas containing remaining livestock (i.e. dairy herd, horses, pet cattle) and will be designed specifically to be able to withstand interference and trampling by stock. Where practicable, and with the agreement of householders, small amounts of bait in open containers will be placed within buildings in inaccessible areas of kitchens, pet food storage areas and pantries. Where possible, bait trays will also be put in accessible roof spaces and under-floor cavities. All bait trays and bait stations will be monitored regularly and bait replenished as necessary for approximately 100 days after the second baiting (this could be longer if surviving rats or mice are detected). Bait in these locations will not be exposed to weathering, and so any remaining bait will be removed after approximately 100 days or after mice or rats are no longer detected. The bait stations will be set close enough together such that individual rats and mice can come across at least one station during their nightly movements. Rats are wide-ranging and can be eradicated using a grid spacing of 25 m. Mice, however, are not as wide-ranging, and require a grid spacing as close as 10 m. It is expected that the combination of hand broadcasting and initial setting of bait stations will take approximately 5 days each (coinciding with the aerial application).

Community consultation is currently in progress to ascertain the buffer zones required for each property (i.e. 30 m or 150 m) and whether bait stations are permitted to be used on individual properties. Consequently, at this stage the exact area of the island scheduled for aerial vs hand broadcasting distribution methods is not known. However according to the shaded areas illustrated on the LHIB figure in **Appendix F**, approximately 80% of the island is scheduled for aerial broadcasting and the remaining 20% of the island will require a combination of hand broadcasting and bait station distribution methods. Assuming a three-dimensional surface area of 2100 ha (refer to **Section 2.1**), this corresponds to approximately 20,160 kg of pellets to be distributed via aerial broadcasting for the first application, and 13,440 kg for the second application (a total of 33,600 kg of Pestoff 20R pellets via aerial broadcasting). Assuming a total of 42,000 kg of pellets is required for the entire REP, this would result in 8,400 kg of pellets to be distributed via hand and bait station methods.

During and following completion of the proposed REP, rodent and non-target species carcasses will be collected where possible and be buried, incinerated on the island or transported back to the mainland for disposal. Due to the island's rugged and inaccessible terrain, it will not be possible to collect the carcasses across the whole island. Bait stations and unused Pestoff 20R pellets will be transported back to the mainland for sale or for disposal at an appropriately licensed facility (LHIB, 2016). Emptied Pestoff 20R bags may be disposed of in a similar manner as discarded bait pellets or they may be incinerated on LHI in accordance with legal requirements (LHIB, 2016).

1.2 Site Visit

A site visit was conducted by Ramboll Environ representatives Dr Robert DeMott and Dr Belinda Goldsworthy between 8 and 11 November 2016. Mr Edward Jansson from the OCSE accompanied Ramboll Environ during the site visit. Select photographs taken during the site visit are provided in **Appendix B**. A summary of the tasks undertaken during the site visit is presented below:

- *Meetings with LHIB*: Ramboll Environ and OCSE met with representatives from the LHIB responsible for coordination of the proposed REP and water management on the island to obtain information necessary to prepare this HHRA.
- *Tour of the island*: between 8 and 11 November 2016, Ramboll Environ visited a number of locations on LHI to gather information relating to potential exposure scenarios to be assessed in this HHRA. These locations included:
  - LHI Central School (Photographs 7 and 8, Appendix B);
  - Playground on Lagoon Road (Photograph 23, Appendix B);
  - Foreshore and beaches including Ned's Beach (Photograph 13, Appendix B), Blinky Beach (Photograph 12, Appendix B), King's Beach (Photograph 14, Appendix B), Lagoon Beach (Photograph 11, Appendix B) and Old Settlement Beach;
  - Areas of potential flooding e.g., airport, near Capella lodge;
  - Major stream systems including Soldier Creek (Photograph 29, Appendix B), Cobby's Creek and Old Settlement Creek (Photograph 30, Appendix B);
  - Wilson Gower Memorial Hospital;
  - Bowling Club (Photograph 9, Appendix B) and adjacent sports ground (Photograph 10, Appendix B);
  - A variety of groundwater bores and rainwater tank systems; refer to **Section 2.13** for further information (Photographs 16 – 22, inclusive, Appendix B);
  - Commercial nursery operated by Kentia Fresh (Photograph 24, Appendix B);
  - Paddocks currently used by cattle (Photograph 15, Appendix B), and dairy farm location
  - Central community area with community hall (Photograph 26, Appendix B), restaurants, post office and tourist shops;
  - Kentia palm plantations; and
  - Waste management facility (Photograph 25, Appendix B).
- *Community Consultation Sessions*: two community consultation sessions were conducted on 9 and 10 November 2016, and approximately 45 residents attended the sessions over two days. Refer to **Section 2.5** for further information regarding the community consultation sessions.

1.3 HHRA Objective

The objective of the HHRA is to characterise the potential human health risks to residents and visitors on Lord Howe Island due to use of Pestoff 20R pellets containing the ingredient brodifacoum, during and following the rodent eradication program. Both short-term (acute) and longer-term (subchronic) exposures and their corresponding health risks are considered.

The HHRA risk characterisation also considers the potential human health risks should the proposed eradication program not proceed, and current or enhanced management practices to be implemented instead.

1.4 HHRA Process and Methodology

HHRA is used to inform and assist decision-makers in managing chemical exposure issues with careful consideration of site-specific circumstances. It is used to estimate, in a way that is adequately protective of health, the potential for chemical exposures to represent a risk of adverse effects on the health of populations potentially exposed to it. Since the goal is to inform decision-makers regarding safe choices and approaches to chemical usage or management, HHRA intentionally does not attempt to establish an upper limit of exposure above which adverse effects are expected, but conversely, employs criteria adjusted so that they are expected to be safe for foreseeably exposed groups, including sensitive subgroups. In other words, comparisons are made to criteria known to be safe, not exposure levels reflecting a threshold at which effects are expected. Margins of safety are built into the process to achieve this. HHRA in this form cannot serve as a means to evaluate health conditions reported by individuals and, thus, is not a substitute for evaluation by a medical professional for individuals concerned about their specific health status.

HHRA in this context is achieved by protectively projecting the dose that individuals might receive through exposure scenarios that reflect the nature of chemical use and how humans can come in contact with the chemicals. These include incidental exposure to impacted soil, sediment and/or water as a result of everyday activities, consumption of food items containing the chemicals, and direct contact to chemical products. This estimated dose can then be compared against doses that are derived to be protective against any adverse impacts to health, as published by authoritative bodies and health protection agencies. These comparison doses are chosen specifically based upon the most sensitive type of potential effects for the chemical.

This HHRA was undertaken in accordance with the Australian guideline for conducting human health risk assessment as outlined in enHealth (2012) *Environmental Health Risk Assessment, Guidelines for assessing human health risks from environmental hazards*. *Commonwealth of Australia*. Modifications were incorporated to address factors related to the circumstances that this is a prospective HHRA of a specific pesticide use that is currently proposed. Existing conditions on the island reflect prior rodent management programs, but not existing environmental impacts from the eradication program. In addition, the HHRA includes an evaluation of acute, direct ingestion of bait pellets, which is a modification since this type of scenario is not typical for evaluating chemicals already released in the environment.

The risk assessment process adopted for this HHRA follows the enHealth (2012) guidance, and is illustrated in **Flowchart 1** on page 18.

1.4.1 Analysis of Uncertainty

Inherent in each step of the risk assessment process are uncertainties that may ultimately affect the final risk estimates and conclusions. Uncertainties may exist in many areas including the information used to characterise chemical usage and distribution, estimation of potential exposures and derivation of toxicity criteria. In general, uncertainties may result in either an over or under-estimation of risks. However, in conducting an HHRA, where uncertainties are recognised, a protective approach and assumptions are adopted in order that the final results are expected to overestimate rather than underestimate potential exposures and risks.

A discussion of the uncertainties in this HHRA for Lord Howe Island is discussed after each corresponding section throughout the report.

1.5 Report Structure

This HHRA follows the guidance listed in **Section 1.4** and the HHRA process illustrated in **Flowchart 1** on page 18, and this HHRA report has been structured to reflect these risk assessment stages including:

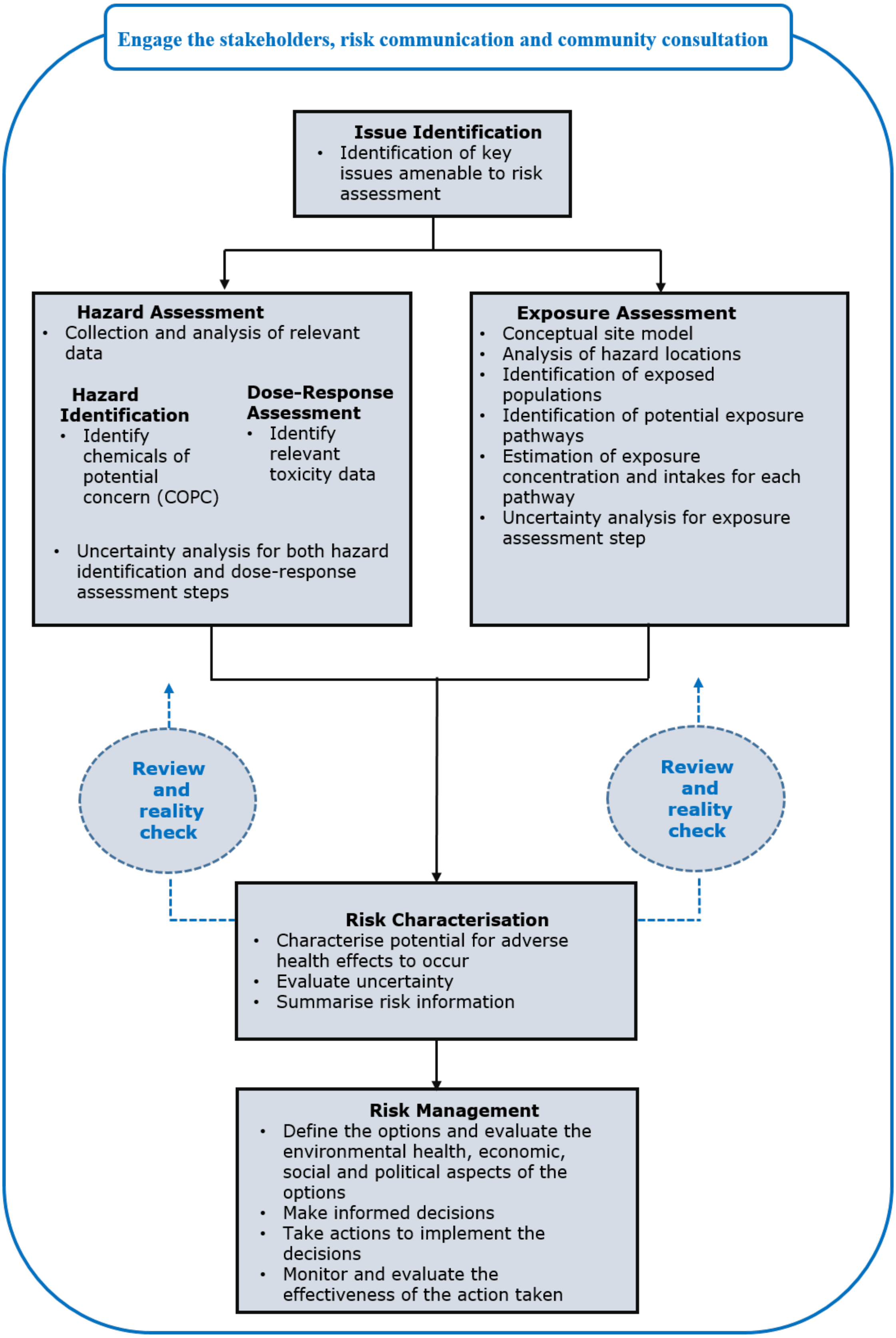
- Section 2: Lord Howe Island Description
- Section 3: Issue Identification
- Section 4: Data Review and Evaluation (including Conceptual Site Model)
- Section 5: Hazard Assessment (Hazard Identification & Dose-Response Assessment)

- Section 6: Exposure Assessment
- Section 7: Risk Characterisation
- Section 8: Derivation of Environmental Criteria
- Section 9: Sensitivity Analysis
- Section 10: Conclusions
- Section 11: References
- Section 12: Limitations

Supporting risk assessment information used to form conclusions in this HHRA is provided in the following Appendices:

- Appendix A: Figures
- Appendix B: Site Visit Photographs
- Appendix C: Risk Assessment Algorithms
- Appendix D: Issues Raised by the LHI Community
- Appendix E: Sensitivity Analysis

Flowchart 1: Environmental Health Risk Assessment Model (enHealth, 2012). Image used by permission of the Australian Government. Environmental Health Standing Committee (enHealth), Environmental Health Risk Assessment: Guidelines for assessing human health risks from environmental hazards, Australian Health Protection Principal Committee, Canberra, 2012. Graphic design by Zoo Advertising, Canberra.



2. LORD HOWE ISLAND DESCRIPTION

Information presented in this Section was obtained from the following sources:

- Australian Bureau of Statistics (2011) for Lord Howe Island
- Destination NSW (2014) LHA Profile – Lord Howe Island. Overview, four year annual average to the year ending September 2014.
- LHIB (2016) Environment Protection and Biodiversity Conservation (EPBC) Referral, and associated attachments.
- LHIB (2016) Lord Howe Island Rodent Eradication Project. DRAFT Public Environment Report, EPBC 2016/7703. 19 October 2016.
- Surface Geology and Soil. Lord Howe Island Board Environmental Study, prepared by Crown Lands Office, Sydney.
- LHIB (1998) Lord Howe Island Flood Study, Summary Report. June 1998.
- LHIB (2015) Drinking water quality assurance program. Version 2.0. Prepared by Atom Consulting.
- LHIB (2015) Hand drawn monitoring well installation details for wells MW1 to MW9. August 2015.

2.1 Location and Size

Lord Howe Island is located 600 km off the coast of Port Macquarie in the Tasman Sea (31° 33′ S, 159° 05′ E) on the NSW north coast. It is a crescent shaped island measuring approximately 10 km long and between 2 km and 0.3 km wide with a two-dimensional area of 14.55 km^2 (or 1455 ha) (**Figure 2, Appendix A**). It should be noted that the total treatment area for the REP is 2100 ha which represents the three-dimensional area of the island including the cliffs and mountains regions.

The Lord Howe Island Group (LHIG) comprises Lord Howe Island, Admiralty Group, Mutton Bird Islands, Ball's Pyramid, and associated coral reefs and marine environments.

2.2 Climate

A summary of the key climate statistics obtained from the Australian Government Bureau of Meteorology (BOM) website, for the past 28 years (1988 to 2016) is presented in **Table 1**. These data were collected from a weather station located at LHI's airport and is current as of 23 November 2016.

Table 1 Key Climate Statistics for Lord Howe Island, 1988 to 2016 (BOM, 2016)

Climate Statistic	June	July	August	September
Rainfall (mm)				
Minimum	75.4	80.2	22.4	45.4
Maximum	562.0	264.2	286.0	201.4
Mean	170.1	144.1	111.5	117.4
Mean no. of days of rain ≥1mm	17.1	17.4	14.9	11.8
Temperature (°C)				
Mean Minimum	14.9	13.9	13.5	14.6
Mean Maximum	19.9	19.0	19.0	20.0

Climate Statistic	June	July	August	September
Wind speed (km/h)[a]				
Mean 9am wind speed	21.9	21.8	21.5	21.0
Mean 3pm wind speed	22.5	23.9	23.0	22.4
Mean Relative Humidity (%)[b]				
Mean 9am relative humidity	66	67	65	68
Mean 3pm relative humidity	66	66	64	68

Notes:

a) Mean wind speed for years 1988 to 2010

b) Mean relative humidity data for years 1989 to 2010

2.3 World Heritage Listing

The LHI Group was inscribed on the World Heritage List in 1982 owing to its "*outstanding examples of oceanic birds of volcanic origin containing a unique biota of plants and animals, as well as the world's most southerly true coral reef. It is an area of spectacular and scenic landscapes encapsulated within a small land area, and provides important breeding grounds for colonies of seabirds as well as significant natural habitat for the conservation of threatened species. Iconic species include endemics such as the flightless Lord Howe Woodhen (*Gallirallis sylvestris*), once regarded as one of the rarest birds in the world, and the Lord Howe Island Phasmid (*Dryococelus australis*), the world's largest stick insect that was feared extinct until its rediscovery on Balls Pyramid*".

In 2014, the International Union for Conservation of Nature (IUCN) undertook a World Heritage property outlook assessment and considered that the rodents presented a "*high threat*" to the LHIG World Heritage values, and recommended implementation of a rodent eradication program to address the threat, to prevent the LHIG being placed on the "World Heritage in Danger List" (IUCN, 2014).

On 30 June 2016, a delegate for the Minister for the Environment (Commonwealth) determined that the proposed REP be assessed by a Public Environment Report in order to obtain approval since the proposed REP has the potential to have a significant impact on matters of National Environmental Significance that are protected under the Commonwealth *Environment Protection and Biodiversity Conservation Act* 1999 (the EPBC Act). The matters of National Environmental Significance includes LHI's listing as a declared World Heritage property. The draft Public Environment Report was completed by the LHIB on 19 October 2016.

2.4 Lord Howe Island Layout

Approximately 3.98 km^2 of the total area of the island comprises the low-lying settlement area containing residential housing, medical facilities, restaurants, shops, tourist lodges, a school, museum, Bowling Club, waste management facilities, recreational facilities, churches and private and commercial agricultural areas. The majority of the population lives in the northern portion of the settlement area while the sandy, semi-enclosed sheltered coral reef lagoon lies along the west coast. The highest mountain on the island is Mount Gower with an elevation of 875 m, which is located on the south coast dominated by forested hills. North of the settlement area is another forested hilly area that extends to the northern end of the island (**Figure 2, Appendix A**)

The Lord Howe Island Group comprises 28 islands, islets and rocks. Apart from Lord Howe Island itself, the most notable of these is the volcanic and uninhabited Ball's Pyramid which is approximately 23 km to the southeast of LHI. To the north of the main island lies the Admiralty Group, a cluster of seven small uninhabited islands.

2.5 Lord Howe Island Community Profile and Consultation Sessions

Community Profile

According to the Australian Bureau of Statistics (2014), the resident population is 396 people (males 199, females 197) and the average age of the population is 43.6 years of age. Children aged 0-14 years comprise 17.7 % of the population and adults aged greater than 55 years comprise 32.4% of the population. Of the occupied residential dwellings, 83.7% are separate houses, 2.2% are semi-detached, 11.1% are flats, units or apartments and 3.0% comprise other structures.

The major source of external income is from tourism and the overseas sale of Kentia palm seeds and seedlings. Feral goats, pigs and cats have been eradicated from the island. Domestic cats are not allowed and dogs are allowed only under strict guidelines. Dogs are required to undergo behavioural training and must be kept at normal places of residence. Goats are not allowed on the island. Any goat currently on the island can only be kept with the permission of the LHIB and only if it is a doe or a desexed buck. Only day-old chicks certified as being free of pests and disease are given approval to be imported to the island by the LHIB. Chickens are expected to be controlled such that they do not stray off of managed properties. About 10 % of the island's forest have been cleared for the grazing of cattle and growing of vegetables such as radish, turnips, silverbeet, pumpkins, potato, eggplant, spinach, rhubarb, herbs, pawpaw, oranges, limes and lemons.

Lord Howe Island Central School provides for the teaching and learning of all students on the island from Kindergarten to Year 6, and in conjunction with Camden Haven High School Distance Education manages all secondary students on the island from Year 7 to Year 12. Ramboll Environ visited the LHI Central School during the November 2016 site visit and observed the school's playgrounds (**Photograph 7, Appendix B**) and vegetable garden which is irrigated with tank rainwater (**Photograph 8, Appendix B**). From discussions with school teachers, it is understood that the LHI Central School has a 'bare foot policy' allowing students to attend the school without shoes. During breaks, students can play within the schools grounds or the adjacent foreshore area. The expectation that children could be outdoors barefoot was incorporated into the assumptions of the HHRA. Several bait stations monitored by LHIB were observed on the school property during the site visit.

LHI Visitor Population

According to Destination NSW (2014), approximately 32,000 tourists visit LHI each year and this is limited to 400 visitors at any one time in order to relieve pressure on the island. The majority of visitors stay overnight, and 31% of the visitor population are 55 years of age or older. On average, tourists stay 6 to 7 nights per visit. The most popular time to visit the island is between September and June which has a typical maximum temperature of 25°C, however even in the winter months (July and August), the days can be sunny and warm with an average temperature of 19°C. This suggests that fewer visitors are likely to be exposed during the proposed period of the REP (June to November) unless weathering of the broadcasted baits prolongs the potential exposure period.

Community Consultation

During the site visit conducted by Ramboll Environ in November 2016 (refer to **Section 1.2**), two community consultation sessions were undertaken to provide the LHI community the opportunity to learn more about preparation of this HHRA and to provide input regarding their thoughts about the types of exposures that could occur in conjunction with the proposed REP and their related concerns. The consultation sessions were conducted on 9 and 10 November 2016, so the residents could choose a suitable time to attend (similar information was provided in both sessions and different sets of concerns and suggested types of exposure emerged from the residents providing feedback in the separate sessions). **Photograph 26, Attachment A**, illustrates the community consultation setup that was conducted in the LHI Community Hall.

Human health related issues raised during the community consultation sessions are presented in **Appendix D**.

2.6 Existing Medical Facilities

Gower Wilson Memorial Hospital is the only medical/nursing facility on the island. The building contains three inpatient beds, one of which is currently used for acute medical/surgical admissions, a pharmacy and medical equipment such as digital x-ray and ultrasound machines. Visiting specialist doctors and dentists consult sporadically over the year, with more complex cases being treated on the mainland.

Ramboll Environ visited the LHI hospital in November 2016 and undertook a tour of the medical facilities accompanied by the resident physician. It is understood that a number of residents are currently taking warfarin medicinally at an average concentration of 5 mg per day. Monitoring for overexposure of these patients to the blood thinning effects of the anticoagulant warfarin (prothrombin time monitoring) is routinely conducted locally on the island by the medical team, and frequency of monitoring could readily be increased during/following the proposed REP at a patient's request. Because the anticoagulant effects of brodifacoum occur via the same mechanism as warfarin, patients on warfarin therapy are recognised as a potentially sensitive subpopulation. In addition to the availability of monitoring for these patients, or other residents concerned about anticoagulant effects from brodifacoum, the standard and effective treatment to counteract anticoagulants operating via this mechanism (Vitamin K) is available and can be administered locally at the hospital.

2.7 Terrestrial Ecology

The island's isolation and its varied landscape of mountains, valleys, hills, lowlands and sea-cliffs have resulted in a diverse array of habitat types supporting many distinctive flora and fauna groups. The information in this Section has been summarised to provide an overview of LHI's terrestrial ecology. The flora and fauna of LHI is not consumed by residents or visitors, and is therefore not of concern for this HHRA.

LHI's Flora

LHI provides habitat for 241 species of indigenous plants of which 113 (47%) are endemic to the island group including four palm species, the most famous of which is the Kentia Palm (*Howea forsteriana*). The banyan tree (*Ficus macrophylla ssp*. *Columnaris*) with its numerous trunks is one of the most noticeable trees on LHI with its huge size and habit of dropping aerial roots which form new trunks. The pandanus tree (*Pandanus forsteri*) with its many prop roots several metres high, forming a teepee structure, can be found along creek beds and soaks of the island. There are ten species of orchids on LHI including the bush orchid (*Dendrobium macropus*) which grows as an epiphyte on the trees and rocks of the lowlands.

Fifty-seven species of ferns have been recorded on LHI, including four tree fern species from the genus Cyathaea which are endemic to the island and mainly found growing around the southern mountains. Ferns are especially abundant on the summit of Mount Gower where the majority of tree trunks and rocks are covered in mosses and ferns.

In summer, the mountains slopes provide habitat for a range of flowers such as the spiky mountain rose (*Metrosideros nervulosa* and *M sclerocarpa*) and white flower spikes of the Fitzgeraldii tree (*Dracophyllum fitzgeraldii*). Some plants growing on LHI have colourful fruits such as the red berries of the berrywood tree (*Ochrosia elliptica*) or the orange berries of the Christmas bush (*Alyxia ruscifolia*).

LHI's Fauna

Due to the distance of LHI from the mainland (~600 km), indigenous large vertebrate animals are absent. The land vertebrates apart from the birds are two species of lizards (Lord Howe Island skink *Oligosoma lichenigera* and Lord Howe Island gecko *Christinus guentheri*) and the large forest bat *Vespadelus darlingtoni.* The large forest bat is the only indigenous mammal remaining on the island. The endemic long-eared bat *Nyctophilus howensis* is presumed extinct.

The Lord Howe Island skink and gecko are rare on the main island but can be seen on the offshore islets including Blackburn Island, Ball's Pyramid and Roach Island. Invertebrates, being much smaller and lighter, travel over large ocean distances more easily and so the island has small invertebrate indigenous fauna such as insects, spiders and snails. These include the Lord Howe Island phasmid *Dryococelus australis,* Lord Howe placostylus (*Placostylus bivaricosus),* Whitelegge's land snail (*Pseudocharopa whiteleggei),* Masters' charopid land snail (*Mystivagor mastersi),* Mt Lidgbird charopid land snail (*Pseudocharopa lidgbirdi)*, and the magnificent helicarionid land snail (*Gudeoconcha sophiae magnifica).* On Lord Howe Island there are approximately 50 species of land snails. Over 100 species of spiders have been identified on Lord Howe Island and most are small and rarely seen, but the large golden orb weaver (*Nephila clavipes)* can be seen during summer. The island has one endemic cicada *Cicadidae*. During summer many species of beetles are active; the largest is the brown, 7cm long cerambid beetle (*Monochamus urussovi)*, whose larvae are long white "witchetty grubs" that eat into the wood of trees.

The seven land bird species currently present on the LHI are the emerald ground dove (*Chalcophaps indica)*, sacred kingfisher (*Todiramphus sanctus)*, buff banded landrail (*Gallirallus philippensis*), two endemic species – the Lord Howe Island woodhen (*Gallirallus sylvestris)* and the Lord Howe Island white-eye (*Zosterops lateralis tephropleurus)*; and two endemic subspecies – the Lord Howe Island currawong (*Strepera graculina crissalis)* and the Lord Howe Island golden whistler (*Pachycephala pectoralis contempt)*.

Introduced land bird species on LHI include the whitefaced heron (*Egretta novaehollandiae*) European songthrush (*Turdus philomelos)*, blackbird (*Turdus merula)*, nankeen kestrel (*Falco cenchroides)*, Australian magpie-lark (*Grallina cyanoleuca)*, common starling (*Sturnus vulgaris)*, masked owl (*Tyto novaehollandiae)* (introduced to kill the rats), mallard-cross Pacific black duck, welcome swallow (*Hirundo neoxena)*, eastern swamphen (*Porphyrio melanotus)* and masked lapwing (*Vanellus miles)*.

2.8 Surrounding Marine Environment

LHI has a mix of temperate and tropical marine species including a coral reef enclosing a lagoon on the western side of the island. During winter, cool temperate ocean currents surround LHI and the larvae of many organisms from cool southern parts of Australia are transported to the island. During summer, the warm East Australian Current flows down from the Great Barrier Reef, transporting tropical marine larvae to the island where they colonise around the island.

Over 500 fish species have been recorded at LHI with particular abundance of angelfish (*Pterophyllum)*, butterfly fish (*Chaetodontidae)* and wrasses (*Labridae)* found in the shallow waters in and around the coral reefs. Temperate fish species include the kingfish (*Seriola lalandi)*, trevally (*Caranx ignobilis)*, salmon (*Salmo salar)*, bluefish (*Pomatomus saltatrix)* and several tuna species (*Thunnini)*. Small reef sharks such as *Carcharhinus melanopterus* are occasionally seen at Ned's Beach on dusk, and in The Lagoon at night. The most common starfish at Lord Howe Island is the seven-armed starfish *Luidia ciliaris*. The crown-of-thorns starfish (*Acanthaster planci)* are found in deeper waters around the island, but currently not in large populations.

Several species of heart urchins *Spatangoida* are found in the rock pools, the most common are the red-tipped urchin (*Heliocidaris tuberculate)* and the spine needle urchins (*Diadema setosum).*

Holothuroidea is the most common sea cucumber species at LHI which grows to 40 cm long. The marine snails can be found in a variety of habitats from the deep water to cliffs exposed at high tide. The most common marine slug is the sea hare (*Aplysia spp)* which has a mottled brown and green appearance, and can grow up to 20 cm in length. It lives mainly in shallow water and rock pools. Many species of crabs inhabit the coral and rocky reefs of LHI including the large swift-footed rock crab (*Leptograpsis variegatus)*, ghost crab (*Ocypodinae)* and hermit crabs (*Paguroidea)*.

The information in this Section has been summarised to provide an overview of LHI's marine ecology. It is understood that fish species such as garfish, trevally and bluefish are regularly caught by residents and visitors for consumption purposes and exposure via this pathway is discussed in **Section 4.4.3.5** and **Section 6.1.7**.

2.9 Topography

The topographic outline of LHI is roughly crescentic or "boomerang-shaped" and comprises a number of undulating rocky areas such as the Admiralty Islets to the north; Mutton Bird Island to the east; Rabbit or Goat Island within the Lagoon on the west; and the solitary pinnacle, Ball's Pyramid, 28 km to the south east. Lord Howe Island was primarily created from three high volcanic ridges, with the highest points on the island being Mount Gower (875 m) and Mount Lidgbird (777 m). The southern mass comprises the area around the two highest mountains, the central mass forms Mount Lookout; and the most northerly of the masses forms the North Ridge. The intermediate depressions are formed of low undulating rises. The shore frontages are flat and usually open but occasionally densely wooded.

The North Ridge is separated into a series of semi-detached peaks. The north-east end of this ridge terminates in the North Peak, or Pools Lookout, a round hill of 218 m. Following the cliffs towards the west is a semi-isolated hill called Mount Eliza which has the appearance of a conical hill cut vertically in half, hollowed out towards the sea. The only gully indentation is near Phillip Bluff, where a short but deep water-way runs in under Mount Eliza. The second spur proceeds from near the centre of the North Ridge, and projects as a round sloping promontory into the Lagoon. Between its western side and Phillip Point is enclosed the North Bay, forming the most northerly arm of the Lagoon, and protected from the heavy south-west seas which at times break upon this part of the island, by one shore end of the coral-reef. On the eastern side of this promontory is a sub-marine depression in the Lagoon, known as the Boat Pool.

The headland is a prolongation of the coral-sand rock plateau. Middle Beach Bay is a small harbour, and is the only landing-place for boats that can be relied upon in all seasons and weather. From Middle Beach, following the coast-line around to Observatory Point and the rocky flanks of Mount Lookout, Blinkenthorpe Bay is approached, terminating to the south-east in Mutton Bird Point. The Lagoon on the west coast is about 5.3 km in length, with an average breadth of half to 1.2 km but narrowing very much towards its southern end.

There are eight Admiralty Islets, six in the main cluster, and two more or less detached representing North Island. The central and largest islet is about 790 m long, 91 m high, steep, and precipitous on its eastern side.

Mutton Bird Island is a quadrangular, rocky, and inaccessible islet, 11 km east of Blinkenthorpe Beach, 80 m high, 36 m length with a central dome-like rock. Close to, but separated from King Point, the southern extremity of LHI, is a small circular islet, known as Gower Island, with deep water immediately adjacent to it. The only other islet contiguous to LHI is Goat or Rabbit Island, within the Lagoon, an oblong piece of land 34.2 m in height. Its outer or western end gives attachment to a portion of the fringing reef.

Ball's Pyramid is situated 28 km to the south-southeast of LHI and has an outline of a pyramid and rises without a break 553 m from the ocean.

Figure 3 in **Appendix A** illustrates the location of the features described in this section.

2.10 Drainage and Flood Potential

The island has three main catchments including:

- The basin draining into Kings Beach which consists of cleared grazing land on the lower slopes with steep, naturally forested areas in the upper catchment. The total area is 111 ha.
- The basin which includes the airport and golf course.
- The main settlement area of the island extending from Pinetrees Resort to Stevens Reserve. This catchment consists of a combination of cleared land partially covered with

low density urban development and agriculture/pasture and disturbed forest areas. There is no natural drainage outlet or flood over path to the ocean in this basin, rather flood waters infiltrate through the subsurface. The total catchment area is 118 ha.

Major flooding of these three catchment areas was observed during severe storms in January and June 1996. In 2015, significant resurfacing and drainage improvements were made to the airport and main settlement area to redirect stormwater to the coast.

There are three main stream systems on the island including Soldier Creek (**Photograph 29**, **Appendix B**), Cobby's Creek and Old Settlement Creek (**Photograph 30, Appendix B**) which were observed by Ramboll Environ during the November 2016 site visit. All three reportedly have dry reaches seasonally and can also be tidally influenced. The airport and Kings Beach basin areas were noted to have permanent flood markers. A number of ephemeral streams are also located on the mountainous and coastal regions of the island.

2.11 Geology

Lord Howe Island is a remnant of an extinct shield volcano, dating back 7 million years and has been eroded to one-fortieth of its original size. The island group represents the exposed peaks of a large volcanic seamount, which is approximately 65 km long by 25 km wide and rises from ocean depths of over 1800 m. The Lord Howe Island group is located near the southern end of a chain of seamounts which extends over 1000 km.

Consequently, the underlying regional geology of LHI comprises tuffs, breccia and basalts, with widespread intrusion of basaltic dykes. The island is dominated by the basalt peaks of Mount Lidgbird and Mount Gower, at the southern end of the island.

LHI's settlement area surface geology is dominated by North Ridge Basalt and Ned's Beach Calcarenite with, comparatively minor inclusions of undifferentiated alluvium (gravel and clay) and alluvial clay. The coastal areas comprise Aeoilan Calcareous Sands and Alluvial and Marine Calcareous Clays. Surface soil in the coastal area comprises a mix of sands on the coastal fringes (e.g. stratified marine and alluvial sand), clays (e.g. brown friable clays), and gravel (e.g. brown structured clays and gravel).

In August 2012, nine groundwater monitoring wells were installed by LHIB to monitor groundwater and are located along the western coast line between Old Settlement and Cobby's Corner. Monitoring well installation construction logs identified that the subsurface geology encountered comprised predominately brown/yellow medium coarse-grained sand, with shell/coral and clay inclusions, down to the maximum depth of the well (7.0m below ground level (bgl)) or when augur refusal was encountered on a 'calcarenite' layer.

2.12 Hydrogeology

The depth to groundwater measured in the nine groundwater monitoring wells installed by the LHIB was between 0.99 m bgl (MW3 at the sports oval/bowling club) and 3.75 m bgl (MW5 at Middle Beach).

Based on the relatively narrow width of the island in the central, non-mountainous area and the presence of hills and an elevated ridgeline along roughly the centre of the long axis of the island, groundwater is expected to flow generally toward both the Lagoon and the ocean from the west and east sides of this rise, respectively.

2.13 Groundwater Extraction Wells

Information obtained from the LHIB indicates that there are 40 groundwater bores installed across the island near private residences, tourist lodges (e.g. Pinetrees, Leanda Lei, Beachcomber, Blue Lagoon, Somerset) and public facilities such as the airport, Golf Club, Church of England, and the medical facility. These wells are predominately located along the western side of the settlement area. Of these 40 bores, seven comprise Spear Point installations whilst the remainder are hand dug wells. The total depth of these bores is understood to range between 2.5 m and 7.5 m bgl. LHIB collects groundwater samples from these 40 wells twice a year for the analysis of pH, nutrients, salinity, total dissolved solids (TDS), sodium chloride and total coliform. Refer to **Table 2** for a summary of the groundwater analytical results from a select number of locations.

During the site visit (refer to **Section 1.2**), it was noted that private groundwater extraction wells have been installed using a variety of casing methods including concrete collars (**Photograph 16** and **18**), 44 gallon drum collars, and rock walls (**Photograph 22**). It is understood that some private extraction wells are flush with the ground surface increasing the potential for surface water runoff to enter these wells during periods of heavy rainfall (**Photograph 17**). These extraction wells were primarily dug by hand, and installed prior to the use of rainwater tank systems.

2.14 Source of Drinking-Water and Filtration Systems

There is no central municipal water supply for residents on Lord Howe Island. The LHIB operates a decentralised potable water supply system of rainwater tanks of potable water for public areas (e.g. airport, public hall), non-potable water supply for public areas (e.g. jetty, playground), its own operations (e.g. research facility, waste management facility) and houses owned by the LHIB (e.g. medical facility, government house). A Drinking Water Quality Assurance Plan was prepared in 2015 for the LHIB which outlines the processes and procedures to be followed to ensure safe drinking water is provided on the island.

Businesses and residents on LHI are responsible for their own water supplies.

The main source of potable drinking water is from rain water collected from roof runoff and stored in large water tanks. The storage capacity of tanks operated by the LHIB range between 4 and 28 kilolitres (kL) each, which is also representative of private rainwater tanks owned by residents on the island. During the site visit (refer to **Section 1.2**), it was noted that some rainwater tanks contain a ‘first flush system’ equipped with coarse filtration (**Photograph 19** and **21, Appendix B**). It is understood that some residential rainwater tanks used to store drinking water do not utilise filtration.

Groundwater from most extraction wells (refer to **Section 2.13**) is generally not used for potable drinking purposes except during periods of no rainfall when rainwater collected in the tanks is exhausted. Such events are reported to have occurred infrequently, on an approximately once in a decade timeframe. In drought periods, the LHIB will supply rainwater and bore water to those with insufficient supply. A limited number of groundwater bores are used routinely to supply drinking water and it is understood that this water is treated via multi-stage processes to meet drinking water standards prior to consumption.

The LHIB provides treated drinking water at a number of locations across the island that has been treated using multi-stage filtration down to a 1µm filter and ultraviolet treatment (**Photograph 20, Appendix B**).

A summary of groundwater analytical results from a select number of well and spear point locations is provided in **Table 2**. The LHIB shares the analytical results with the well owners, and recommendations are provided regarding use of the groundwater. Where high salinity and faecal coliform is detected in the groundwater, the LHIB recommends that untreated groundwater is not used for drinking, showering or cooking.

Table 2 Groundwater Analytical Results from a select number of locations; mean concentrations measured between February 2008 and October 2016 (*n* = 17 samples).

Well ID	pH	Turbidity (NTU)	Electrical Conductivity (µS)	Total Dissolved Solids (ppm)	NaCl (%)	E. Coli (MPN/100ml)
Most northerly well (no. 169)	7.15	0.55	3635	1818	6.99	476
Most southerly well (no. 25)	7.3	0.11	1097	550	2.16	54.13
Inland well (no. 156)	7.18	0.01	2188	1062	4.36	55
Bowling Club (well)	7.64	0.83	1283	641	2.61	343
Airport (speer point)	7.45	1.98	1063	367	1.37	<1

3. ISSUES IDENTIFICATION

The Issues Identification process is intended to establish the context for the HHRA by a process of identifying the concerns that need to be addressed, such as "*what is causing the identified concern*?" and "*why is the concern an issue*?" It is a process of communication between stakeholders in the project, and its scope and complexity depend upon the scale of the project and the issues being addressed.

3.1 Nature of the Existing and Historical Management Program Impacts

The rat population on LHI is estimated to be between 63,000 and 150,000 individuals, and the mouse population between 140,000 and 210,000. As described in **Section 1.1.1**, the rats and mice are having a negative impact on the island's flora and fauna and threatening the island's listing as a World Heritage site. In an attempt to manage the rodent population, a control program is currently in place on the island via a baiting program (using coumatetryl) managed by the LHIB and by residents who independently purchase rodenticide products (containing brodifacoum) for personal use on their property (refer to **Section 1.1.1**).

The LHIB has identified that this approach aims to keep the negative effects of the rats and mice within 'acceptable limits', and is quite distinct from eradication. This approach also brings an increased potential for negative impacts caused by the ongoing presence of rodenticide poison in the environment, and the risk of poisoning to non-target species including humans, pets and livestock. There is also concern that the rodents will become resistant to coumatetryl and brodifacoum, as has already been seen with a resistance to warfarin by mice on the island. If resistance to coumatetryl and brodifacoum, developed, eradication would become infeasible and even management of rodent populations in the settlement area would be difficult.

3.2 Nature of the Proposed Rodent Eradication Program Issues

The proposed REP involves the island-wide distribution of the Pestoff 20R pellet containing the active ingredient brodifacoum at a concentration of 20 mg/kg. Due to the steep and heavily forested areas of the island, a variety of distribution methods are proposed including aerial dispersion via helicopter, hand broadcasting, covered bait stations, and open trays containing the pellets inside certain areas of buildings.

The proposed REP has been the subject of significant community debate, plans and reports over a number of years. The LHI community has expressed a variety of concerns about the proposed REP ranging from ecological impacts to financial impacts due to a reduction in tourism. Amongst these concerns are potential human health impacts due to the island-wide distribution of the pellets and the potential for brodifacoum to enter the environment, particularly via aerial broadcasting which is perceived as a difficult to control method of distribution. **Appendix D** summarises the human-health concerns raised by the LHI community during the consultation sessions in November 2016, and via written submissions to the OCSE.

In 2010, a HHRA was completed by Toxikos on behalf of the LHIB to evaluate human health concerns; however some concerns have continued to be expressed about potential human health impacts of the eradication program. Therefore in addition to the Toxikos HHRA, there was requested a need for a fully independent HHRA to be completed with review by an external panel that had specialists in toxicology and public health.

Consequently, to address these human health concerns, the LHIB commissioned an additional HHRA with independent oversight of the process through an Expert Panel chaired by Professor Mary O'Kane (NSW Chief Scientist & Engineer), with members Professor Brian Priestly (Monash University), Professor Steven Leeder (Sydney University) and Dr Chris Armstrong (Office of Chief Scientist & Engineer (OCSE)).

3.3 HHRA Dimensions

This HHRA assesses the potential for exposures above derived safe levels for residents and visitors of Lord Howe Island due to exposure to the chemical brodifacoum contained within a cereal-based pellet proposed to be distributed across LHI as a method to eradicate rats and mice from the island.

During preparation of this HHRA, Ramboll Environ undertook a site visit to LHI to gather site-specific information to assist in preparation of this report. During the site visit, Ramboll Environ engaged with local community members to listen to their health-related concerns about the proposed REP and elicit information about relevant exposure scenarios, and liaised with staff of the LHIB to obtain information relating to the REP, water management, LHI's infrastructure and medical facilities.

During the community consultation sessions facilitated by Ramboll Environ in November 2016 (refer to **Section 2.5**), some of the residents expressed concern relating to health impacts from stress and anxiety experienced due to their concerns regarding the REP. This HHRA focuses on the health impacts directly relating to responses to chemical exposure, and not relating to impacts such as stress and anxiety relating to the REP process. However, the relevance of such indirect effects for individual wellbeing and health is recognised and is identified specifically for OCSE consideration. Since the stresses and anxieties relate to financial, societal and varied family and personal factors beyond just direct chemical effects, a broader type of consideration may be useful to the community.

This HHRA does not assess potential impacts to the flora and fauna (including pets) of the island from the proposed REP. This includes the marine community surrounding LHI. However, the potential for uptake of brodifacoum to edible marine fish and shellfish is considered since this represents a potential exposure pathway for residents and visitors to the island via the collection and consumption of seafood.

3.4 Risk Management Decisions

This HHRA has been prepared independently by Ramboll Environ to inform a report to be prepared by the NSW Office of the Chief Scientist & Engineer regarding the potential health impacts from the proposed REP. It is understood that results and conclusions presented in this HHRA will be considered by the LHIB when deciding how and whether to proceed with the proposed REP.

3.5 Project Stakeholders

The following stakeholders are involved in this project:

- *The Office of the Chief Scientist & Engineer*: was engaged by the LHIB to independently oversee the preparation of this HHRA. Ramboll Environ was engaged by the OCSE to prepare this HHRA.
- *The Lord Howe Island Board (LHIB):* the LHIB is directly responsible to the NSW Minister for Environment, and comprises four Islanders elected by the local community and three members appointed by the Minister. The LHIB engaged the OSCE to independently oversee preparation of this HHRA.
- *The Lord Howe Island Community*: the LHI residential community is described in **Section 2.5**. Feedback on the proposed REP is provided by the LHI community and via the LHIB.
- *Independent expert reviewers*: Professor Brian Priestly (Director, Australian Centre for Human Health Risk Assessment Monash University) and Professor Steven Leeder (Emeritus Professor of Public Health and Community Medicine University of Sydney) will provide an independent expert review of this HHRA.

4. DATA REVIEW AND EVALUATION

4.1 Data Considered in the HHRA

Information and observations obtained during a site visit to LHI conducted by Ramboll Environ in November 2016 were used to prepare this HHRA (refer to **Section 1.2** for a description of the site visit observations). In addition, information from the following reports were used to assess the fate of Pestoff 20R pellets in the environment, and estimate likely concentrations of brodifacoum in a variety of media such as soil, groundwater, ambient air, surface water, fish and plants on LHI:

- Broome KG, Fairweather ACC, Fisher P (2016) Brodifacoum Pesticide Information Review. Version 2016/1. Unpublished report docdm-25436, Department of Conservation, Hamilton, NZ 137p.
- Craddock P (2004) Environmental breakdown of Pest-Off poison bait (20ppm Brodifacoum) at Tawharanui Regional Park, North of Auckland. Winter 2003 Trial. Report prepared for Northern Regional Parks, Auckland Regional Council (unpublished). Entomologica Consulting, Auckland.
- Empson RA, Miskelly CA (1999) The risks, costs and benefits of using Brodifacoum to eradicate rats from Kapiti Island, New Zealand. New Zealand Journal of Ecology, 23(2): 241-254.
- Fisher P, Griffiths R, Speedy C, Broome KG (2011) Environmental monitoring for Brodifacoum residues after aerial application of baits for rodent eradication. In: Veitch CR, Clout MN, Towns DR eds. Island Invasives: Eradication and Management. IUCN, Gland, Switzerland.
- Howald G, Donlan CJ, Faulkner KR, Ortega S, Gelleman H, Cross DA, Tershy BR (2010) Eradication of black rats *Rattus rattus* from Anacapa Island. Oryx 44 (01): 30-40.
- LHIB (2016) Lord Howe Island Rodent Eradication. DRAFT Public Environment Report, EPBC 2016/7703. Lord Howe Island Board.
- Maitland MJ (2012) Shakespear Open Sanctuary animal pest eradication monitoring report #1. Auckland Council, Auckland, New Zealand. 69p.
- Masuda BM, Fisher P, Beaven B (2015) Residue profiles of Brodifacoum in coastal marine species following an island rodent eradication. Ecotoxicology and Environmental Safety, 113: 1-8.
- Pitt WC, Berentsen AR, Shiels AB, Volker SF, Eisemann JD,Wegmann AS, Howald GR (2015) Non-target species mortality and the measurement of Brodifacoum rodenticide residues after a rat (*Rattus rattus*) eradication on Palmyra Atoll, tropical Pacific. Biological Conservation 185.
- Primus T, Wright G, Fisher P (2005) Accidental discharge of Brodifacoum baits in a tidal marine environment: a case study. Bulletin of Environmental Contamination and Toxicology 74: 913-919.
- Vestena C, Walker A (2010) Ipipiri Rodent Eradication 2009 Post Operational Monitoring Report. Unpublished, Docdm-483696 Bay of Islands Area Office, Department of Conservation, Kerikeri.
- Wright RG, Booth LH, Morriss GA, Potts MD, Brown L, Eason CT (2002) Assessing potential environmental contamination from compound 1080 (sodium monofluoroacetate) in bait dust during possum control operations. New Zealand Journal of Agricultural Research, 45:1, 57-65.

4.2 Data Quality and Quantity

During preparation of this HHRA, Ramboll Environ relied upon information presented in the reports listed in **Section 4.1** and did not independently verify all of the written information, the accuracy or precision of the data presented, or the analytical procedures used in the studies. The majority of these studies were noted to be field-based projects, with only a limited number conducted under controlled laboratory conditions. It is recognised that the quality of data relied upon will vary as some information were published in peer-reviewed journals (e.g. Bulletin of Environmental Contamination and Toxicology) whilst others were presented in 'unpublished' reports where the level of peer review is unknown.

The availability of information relating to the presence of brodifacoum following the distribution of rodenticide pellets in the environment is limited, and consequently Ramboll Environ made a number of assumptions in developing the estimates for concentrations of brodifacoum in soil, groundwater, surface water, vegetables, seafood, sediments, tank water and ambient air on LHI (refer to **Table 3**). Furthermore, the fate of Pestoff 20R pellets in the environment is limited to a few studies.

Due to the nature of the data available, this HHRA has set out to incorporate assumptions corresponding to a near-"worst-case' exposure scenario when evaluating potential health risks to residents and visitors to LHI, including protective toxicity reference values and exposure parameters. This approach is considered to account for the limited and variable quality of the data available for use in the HHRA.

4.3 Data Gaps

An assessment of the data gaps identified for conducting the HHRA are presented in **Table 3**.

Table 3 Data Gaps

Data Gaps	Potential Significance	Manner in which data gap is addressed in the HHRA
It is unknown how long it will take the Pestoff 20R pellets to breakdown on LHI following placement in the environment.	The faster the pellet degrades and resembles a mushy form, the lower the chance a child will pick up a pellet and intentionally ingest it.	Information obtained from previous studies which examined the degradation rate of the Pestoff 20R pellets in a variety of habitats and canopy cover will be used to make assumptions regarding pellet degradation (refer to **Section 4.4.1.1**).
It is unknown how long brodifacoum will remain in the soil following degradation of the pellet.	Once the pellet disintegrates, studies have detected brodifacoum concentrations in surface soil. Human receptors have the chance to directly contact soil impacted by the pellet.	Information obtained from previous studies which examined the concentration of brodifacoum in surface soil beneath, or immediately adjacent to, a pellet will be used to make assumptions regarding brodifacoum concentrations in surface soil (refer to Section **6.1.1**).
The amount of dust generated during distribution of the pellet via aerial and hand broadcasting techniques is unknown.	Human receptors on LHI have the potential to inhale dust particles containing brodifacoum during, and immediately after, the distribution of pellets.	Information obtained from previous studies which examined the potential for dust generation during aerial broadcasting of cereal-based pellets will be used to estimate brodifacoum concentrations in ambient air during the REP (refer to **Section 6.1.3**).
The concentration of brodifacoum in groundwater and surface water due	There is a small potential for brodifacoum to enter groundwater and surface water following distribution of the Pestoff 20R	Equilibrium partitioning modelling (as described in ASTM (2010)) between brodifacoum sorbed to soil and soil pore water was used to

Data Gaps	Potential Significance	Manner in which data gap is addressed in the HHRA
to distribution of the Pestoff 20R pellets is unknown.	pellets. Residents and visitors of LHI have the potential to contact groundwater (via extraction) and surface water in streams.	estimate groundwater and surface water concentrations (refer to **Section 6.1.5** and **6.1.6**).
The concentration of brodifacoum in fish tissue for human consumption due to distribution of the Pestoff 20R pellets is unknown.	There is a small potential for brodifacoum to be taken up into fish tissue in the marine environment surrounding LHI. Residents and visitors to LHI have the potential to catch and ingest the fish tissue.	An assumption was made regarding the concentration of brodifacoum in edible portions of fish tissue based on reported concentrations in whole fish samples following aerial baiting programs (refer to **Section 6.1.7**).
The concentration of brodifacoum in vegetables and fruit grown on the island due to distribution of the Pestoff 20R pellets is unknown.	Fruit and vegetables are grown on LHI for consumption by residents and visitors. There is a small potential that a Pestoff 20R pellet is unintentionally dropped into an area used to grow this produce. There is a potential for health risks should brodifacoum be taken up into the produce flesh/skin and consumed by humans.	A 'plant uptake model' was used to estimate the concentration of brodifacoum into vegetables and fruit on the assumption that the plant is grown in soil directly beneath a Pestoff 20R pellet. 'Plant uptake models' are known to intentionally over predict concentrations, and these limitations are discussed (refer to **Section 6.1.8**).
The activity patterns and behaviours of residents and visitors on LHI is not known with any certainty.	When quantitatively assessing the potential for health risks, assumptions regarding human activity patterns and behaviours must be made accounting for circumstances protectively, even if these are unlikely to be realistic (e.g. a child directly contacting soil beneath a degraded pellet or intentionally ingesting a pellet).	To account for this uncertainty, HHRAs make protective assumptions regarding activity patterns and behaviours that tend to consider a 'worst-case' scenario for an overly exposed human receptor. A discussion of this uncertainty is presented in **Section 6.4**.

4.4 Conceptual Site Model

A conceptual site model (CSM) is a site-specific qualitative description of the chemical source (i.e. brodifacoum), the pathway(s) by which the chemical may migrate through the environmental media, and the human populations that may potentially be exposed. This relationship is commonly known as a Source-Pathway-Receptor (SPR) linkage. Where one or more elements of the SPR-linkage are missing, the exposure pathway is considered to be incomplete and no further assessment of that particular pathway is required because there is no exposure via this set of circumstances.

The CSM for the Lord Howe Island proposed Rodent Eradication Program is described in detail below.

4.4.1 Chemical Source

The chemical of concern for this HHRA is brodifacoum which is the active ingredient in the cereal-based Pestoff 20R pellets at a concentration of 20 mg/kg. The Pestoff 20R pellet contains a foodgrade green dye and does not contain the bittering agent denatonium benzoate, commonly referred to as 'Bitrex'. It is understood the pellets will be un-waxed and cylindrical in shape.

Brodifacoum is a second generation anticoagulant, and its physico-chemical and toxicological properties are presented in **Section 5**.

4.4.1.1 Pestoff 20R Pellet Weathering

The Pestoff 20R pellets are made from compressed cereal and are designed to break down following absorption of moisture from soil or rain. Overtime, the pellets swell, crack and then crumble and this process is influenced by temperature, rainfall and invertebrate activity. Mould and fungi can appear rapidly as breakdown proceeds, and once this happens the pellets are less likely to be eaten by non-target species.

Pellets to be distributed via aerial and hand broadcasting methods will not be placed in or under buildings where they would not be subjected to weathering processes. Degradation of the pellet by weathering is understood to be an essential feature of the proposed REP so that no un-weathered pellets remain at completion of the eradication program. It is understood that any pellets not exposed to weathering (i.e. in bait stations or in dwellings) will be collected approximately 100 days after the second treatment. However, LHIB (2016) acknowledge that it is not possible to collect all pellets as some will be within caves/burrows and in inaccessible forested areas.

A condition index (the Craddock Condition Index) for assessing pellet breakdown has been developed which uses an index on a scale of 1 to 6 as follows:

- *Condition 1*: fresh pellets/pellets not discernible from fresh bait
- *Condition 2*: soft pellets. Greater than 50% of pellet matrix is or has been soft or moist. Bait is still recognisable as a distinct cylindrical pellet; however cylinder may have lost its smooth sides. Greater than 50% of bait may have mould. Bait has lost little or no volume.
- *Condition 3*: mushy pellet. Greater than 50% of bait matrix is or has been soft or moist. Greater than 50% of pellet has lost its distinct cylindrical shape. Greater than 50% of bait may have mould, and bait may have lost some volume.
- *Condition 4*: pile of mush. 100% of bait matrix is or has been soft or moist. Pellet has lost distinct cylindrical shape and resembles a pile of mush with some of the grain particles in the bait matrix showing distinct separation from the main pile. Greater than 50% of bait may have mould. Bait has lost some volume.
- *Condition 5*: disintegrating pile of mush. 100% of bait matrix is or has been soft or moist. Pellet has completely lost cylindrical shape and resembles a pile of mush with >50% of the grain particles in the bait matrix showing distinct separation from each other and the main pile. Greater than 50% of bait may have mould, and the bait has definitely lost a significant amount of volume.
- *Condition 6*: bait gone. Bait is gone or is recognisable as only a few separated particles of grain or wax flakes (Craddock, 2004).

A number of studies have examined the breakdown of the Pestoff 20R pellets to characterise its weathering potential and were scored according to the Craddock Condition Index described above. A summary of these studies is provided below:

- In August 2007, the LHIB conducted a study examining 100 baits of 5.5 mm and 10 mm in diameter, under a range of canopy conditions (zero, medium and full canopy) to monitor bait longevity (LHIB Appendix D, 2016). The results showed that baits of both sizes were in the advanced stages of decomposition (at least Condition 4) after 55 days and 164.2 mm of rainfall. Further monitoring showed that all baits had completely disappeared after approximately 100 days.
- Broome *et al* (2016) reported that breakdown studies of Pestoff 20R pellets on temperate NZ islands were completely weathered between 4 weeks and 5 weeks for baits located

without canopy cover, approximately 3 months for baits located on sand dunes, and 6 to 10 months for bait located on bare rock and a bare lava field, respectively. It is assumed that the lack of soil microbes and moisture in the sand dunes and bare rock surfaces resulted in the longer breakdown periods. In theory, these breakdown times could be possible for the sand dune areas on LHI; however LHIB (2016) states that "*Baits not exposed to weathering remain toxic for a long period and any bait not exposed to weathering (i.e. in bait stations or in dwellings) will be collected approximately 100 days after the second treatment*".

- Day (2004) reported that Pestoff 20R pellets degraded rapidly after placement in pasture, and had completely disappeared after 90 days. The study also stated that the baits continued to contain brodifacoum for as long as they were present in the pasture.
- The Craddock (2004) Pestoff 20R bait stability trial reported that most 10 mm pellets had become soft within 48 hours of placement in eight different habitat types, and after 8 days most pellets were beginning to loose shape and had reached Condition 3 or higher representing a mushy pellet. The degradation stages of the pellets after this time varied between and within habitat types but all pellets in the pasture had degraded completely after 110 days.
- Fisher *et al* (2011) reported that 96.5% of Pestoff 20R pellets aerial distributed on Little Barrier Island in New Zealand had completely broken down by 120 days in open grassed areas and this occurred slightly slower in forested areas.

Although the above studies indicate that the Pestoff 20R pellets disintegrate and disappear on the order of around 100 days when exposed to rainfall, the active ingredient brodifacoum will take longer to break down as described in **Section 6.1.1.**

4.4.2 Human Receptors

Both full-time residents and intermittent visitors inhabit the island (refer to **Section 2.5**). When identifying the human receptor(s) of concern for this HHRA, Ramboll Environ considered sensitive human receptors within the population. Sensitive (i.e., potentially highly exposed) human receptor scenarios are chosen when conducting a HHRA because potential health risks identified for the sensitive population are considered to be suitably protective of less sensitive/less exposed members of the population.

The human receptors of concern for this HHRA include:

- *Toddler:* this receptor is considered to be a young child. enHealth (2012b) provides a recommended average body weight of 15 kg for a child aged 2 to 3 years; and these recommendations were assumed to represent this receptor. This age group is considered to be more mobile than a younger child, and therefore has a greater potential to be exposed to impacted media on the island, and is likely to ingest more drinking water than a younger child whom may ingest a greater proportion of milk in their diet. This child is assumed for the HHRA to have minimal parental supervision, and therefore has the potential to pick up a Pestoff 20R pellet lying on the ground or in open bait stations within a house and can be exposed to soil while outdoors.
- *School Child:* this receptor is considered to be a school-aged child. enHealth (2012b) provides a recommended average body weight of 36.5 kg for an Australian male and female child aged 8 to 11 years of age (enHealth, 2012); and these recommendations were assumed to represent this receptor. A school child is specifically considered in this HHRA due to their unique exposure whilst at school and during playtime. It is understood that LHI school children have the option to attend school with no shoes, and play in the Lagoon foreshore area during school breaks. Outside school hours, the child has the freedom to enter the forested areas, rocky shores and beaches of LHI, as well as areas throughout the settlement.
- *Pregnant Female:* this receptor is considered to be a young, potentially pregnant female. enHealth (2012b) provides a recommended average body weight of 66.6 kg for an Australian female aged 19 to 24 years of age; and these recommendations were assumed

to represent this receptor. This receptor was chosen to assess the potential reproductive and developmental effects relevant to a pregnant woman, because warfarin, which has similarities to brodifacoum, has been documented to affect musculoskeletal development during certain windows of pregnancy. While testing with brodifacoum has not produced this effect, due to their similarities, the effects of warfarin are considered, i.e. read-across, for the sake of protectiveness in evaluating brodifacoum. This receptor is considered to spend her days outside undertaking activities resulting in exposure to surface soil and hiking in the forested areas.

- *Adult:* this receptor is considered to be an adult aged 18 years and older. enHealth (2012b) provides a recommended average body weight of 78 kg for male and females aged 18 years and older; and these recommendations were assumed to represent this receptor. This adult is considered to spend their working day outdoors undertaking activities such as mountain or island tours which is likely to have a greater exposure to any residual brodifacoum than an adult working indoors at the museum, restaurants, shops etc.

The older members of the population on LHI are considered to be in the 'Adult' human receptor group, and are known to have a heterogeneous population in terms of their general health. For those with impaired health, there may be a variety of conditions present and they are likely to be higher consumers of pharmaceuticals. The elderly subpopulation, and those taking therapeutic doses of anti-coagulants such as warfarin, that could have particular sensitivity is accounted for in this HHRA via the choice of lowest (most protective) toxicity reference value (TRV) for brodifacoum (that derived for protection of the foetus), even though it is the anticoagulant effects, which correspond to a less protective value, that are actually relevant to this population (explained in detail in **Section 5.1.6.2)**. Accordingly, the potentially different sensitivity of elderly residents and visitors to LHI can be considered to be adequately assessed by the adopted brodifacoum TRV.

4.4.3 Exposure Pathways

In order for the receptors identified in **Section 4.4.2** to be exposed to the chemical brodifacoum within the Pestoff 20R pellets, there needs to be an exposure pathway linking brodifacoum and the exposed human population. An exposure pathway describes the course brodifacoum takes from the Pestoff 20R pellet to the exposed individual and generally includes the following elements:

- a source and mechanism of chemical release;
- a retention or transport medium (or media where chemicals are transferred between media);
- a point of potential human contact with the chemical; and
- an exposure route (e.g., incidental ingestion, dermal contact) at the point of exposure.

A discussion of the possible exposure pathways between brodifacoum and the human receptors of concern for this HHRA is provided below.

4.4.3.1 Exposure via Direct and Indirect Contact with Soil

Children and adult residents have the potential for direct contact (incidental ingestion and dermal contact) with surface soil during their daily activities. The inadvertent ingestion of soil has been identified as a common and important exposure pathway by enHealth (2012) particularly for young children who are prone to ingest soil as they have greater contact with soil during play and have not developed the avoidance strategies of older children and adults. Adults and older children may ingest soil or dust particles that adhere to food, cigarettes, or their hands (US EPA, 2011). Soil ingestion is defined as the consumption of soil resulting from various behaviours including, but not limited to, hand-to-mouth actions, contacting dirty hands, eating dropped food, or consuming soil directly.

Soil may also be inadvertently ingested during vegetable consumption if the food produce is not washed thoroughly enough prior to consumption. During derivation of the Australian Health Investigation Levels for soil, NEPM (2013) considered this pathway and concluded that the soil intake associated with vegetable ingestion "*…is considered only minor in comparison with the soil/dust ingestion rates adopted for adults (50 mg/day) and children (100 mg/day)….and is considered to be adequately encompassed within the level of uncertainty inherent in the ingestion rates adopted. Hence, the additional contribution of soil ingested from home-grown produce has not been considered separately…*". This assumption was also adopted in the HHRA.

Dermal contact with soil is also an important exposure pathway for this HHRA, particularly for toddlers and school children who often have bare feet during playtime and when walking across the island. Adult residents and visitors are also likely to walk throughout the island and in forested area barefoot. When assessing the potential health risk via dermal contact factors such as the area of skin surface exposed, and amount of soil adhering to the skin are important considerations.

As discussed in **Section 6.1.1**, brodifacoum concentrations have been detected in surface soil either directly beneath a Pestoff 20R pellet or within 20cm of a pellet at concentrations between 0.9 µg/g and 0.07 µg/g, at 56 days and 153 days, respectively, post placement of the bait. Once in soil, brodifacoum rapidly and strongly binds to soil with a very low potential for leaching (refer to **Section 5.1.2**). As a conservative approach, this HHRA has assumed exposure to brodifacoum via the incidental ingestion of soil and dermal contact with soil that is immediately adjacent to, or directly beneath, a decaying or decayed Pestoff 20R pellet. This exposure scenario assumes contact with surface soil by hands and feet, and assumes a child or adult will contact the impacted patch of soil beneath/near the degraded pellet every day for 180 days (i.e. the reported number of days taken for brodifacoum concentrations to degrade to concentrations below the laboratory detection limits, refer to **Section 6.1.1**).

4.4.3.2 Exposure via Inhalation of Dust from the Pestoff 20R Pellets

Aerial broadcast of cereal-based pellets has the potential to generate dust in ambient air due to mechanical abrasion in the spreader bucket. This has been demonstrated during an aerial application of cereal-baits containing the pesticide 1080 (unrelated to brodifacoum) across central North Island in New Zealand (Wright *et al*, 2002). Within the baiting zone, this study reported 1080 average concentrations in dust between 0.29 µg/m^2 and 3.81 µg/m^2 the day following the aerial application, with a maximum concentration of 25.2 µg/m^2.

LHIB (2016) states that the Pestoff 20R pellet is manufactured to rigorous specifications so as to be hard enough to withstand mechanical abrasion in a metal bucket spreader with minimal fragmentation, and to have minimal dust residue. However as demonstrated by Wright et al (2002), there is the potential for dust to be generated from abrasion of cereal-based baits during, or shortly after, broadcast by aerial application. Therefore, to be protective, the potential exposures associated with the inhalation of dust particles from the pellets containing brodifacoum will be assessed.

The US EPA (2009) RAGS-F guidance recommends that when estimating risk via inhalation pathways, the concentration of the chemical in air should be used as the exposure metric (e.g. mg/m^3), rather than inhalation intake of a chemical in air based on an inhalation rate and body weight (e.g. mg/kg-day). This is known as the *Inhalation Dosimetry Methodology* which supersedes the previous US EPA (1989) Risk Assessment Guidance for Superfund, Part A inhalation methodology because "*the internal dose to a chemical from the inhalation pathway is not a simple function of the inhalation rate and body weight…".* Rather, the critical factor influencing health risk associated with inhalation is the exposure time.

If airborne dust is generated, children and adults on LHI have the potential to inhale the fine dust particles containing brodifacoum during the period of pellet distribution. LHIB (2016) states that "*the combination of hand broadcasting and setting and arming of bait stations will take approximately 5 days each application (coinciding with the aerial application)….[each] bait drop* *will take approximately two days to complete dependant on weather*". Based on this information it can be assumed that the total time taken to distribute the pellets via aerial and hand broadcasting is a total of 10 days for both applications. As a conservative approach to allow for logistical complications, this HHRA assumes an additional five days to allow for logistical constraints (i.e. a total of 15 days exposure time for exposure to dust).

4.4.3.3 Exposure via Ingestion of Meat, Dairy and Poultry Products

LHIB (2016) states that all cattle intended for consumption purposes will be culled and/or removed from the island prior to the proposed REP. Replacement breeding stock will then be brought to the island when the breakdown of pellet is complete, beginning approximately 100 days following completion of the REP. As discussed in **Section 6.1.1**, degradation of brodifacoum to non-detectable concentrations in soil beneath pellets can take 60-180 days. And the propensity of brodifacoum to adhere to soil limits transport into vegetation (see **Section 6.1.8** and plant uptake model showing approximately 1,000-fold lower concentration in leaf material than soil). Given these circumstances and the small area of soil directly beneath weathered pellets relative to the area over which cattle would graze, the potential for transport to cattle via grazing after the 100-day exclusion period is expected to be below any detectable uptake in new cattle grown to market weight over the subsequent months.

A small dairy herd (approximately 14 animals) is also located on the island, and it is understood that this diary herd will likely remain on the island during the REP and be confined to a small paddock where they will receive supplementary feed during the period that bait is present in the paddock. Baiting within the dairy herd holding paddock will be via the use cattle-proof bait stations.

LHIB (2016) also identifies that all poultry will be removed from the island or culled at least one month prior to the proposed REP. Once the bait has disintegrated and is no longer present, day-old chicks will be brought to LHI to replace those birds removed.

As a consequence of this management strategy proposed by LHIB, brodifacoum is unlikely to be taken up into cattle, cow's milk or poultry and subsequently consumed by residents and visitors to LHI. Further assessment of these potential exposure scenarios will therefore not be considered further in the HHRA.

4.4.3.4 Exposure via Ingestion of Vegetables

Vegetables and fruit are grown on LHI for commercial purposes (Kentia Fresh) and by residents for personal consumption. It is also understood that the Lord Howe Island Central School grows vegetables and fruit on school grounds (refer to **Section 2.5**).

Plants can accumulate chemicals via a number of different pathways, the most important of which is typically absorption by roots where, depending on the nature of the chemical, translocation to other portions of the plant may occur (NEPM, 2013). Uptake of organic chemicals predominantly occurs from the soil solution. In soils where the clay content is relatively low, such as on LHI, the availability of organic chemicals in the soil solution is strongly related to the fraction of organic carbon (MfE, 2011).

Brodifacoum has the potential to be exposed to surface soils where vegetables and fruits are grown via the accidental placement of a pellet or via surface water runoff containing dissolved brodifacoum (albeit at low concentrations, refer to **Section 4.4.3.7**) down hillsides. Some residents have expressed concerns regarding their vegetable patches which are located at the foot of a hill where surface water is known to accumulate (**Appendix D**). Therefore, the potential health risks associated with the consumption of fruit and vegetables, which have the potential to accumulate brodifacoum, by LHI residents and visitors are quantitatively assessed in this HHRA.

4.4.3.5 Exposure via Ingestion of Seafood

During aerial distribution of the Pestoff 20R pellets, there is a potential for the pellets to inadvertently enter the surrounding marine environment when pellets bounce off the steep rocky cliff areas or when baiting locations are along the shoreline. LHIB (2016) states that a deflector arm will be attached to the helicopter spreader bucket to restrict the arc of the swathe to 180° and will be used particularly when baiting the edge of buffer zones and to minimise bait entry into the marine environment. In addition, a 'trickle bucket' option will be used in areas where a thin line of bait application between 5-10m is required.

The depth of water surrounding LHI ranges between <1m in the Lagoon area, and >30m in the environment adjacent to the steep rocky cliffs such as the southern end of Mount Gower. Fish populations, albeit relatively small numbers of them, in these shallow and deeper areas have the potential to ingest pellets before the pellets have the opportunity to disintegrate in the water column which is reported to be less than 15 minutes (Empson and Miskelly, 1999).

Pitt *et al* (2015) reported that between 14% and 19% of brodifacoum bait entered the marine environment up to 7 m from the shore line following an aerial application of pellets across the Palmyra Atoll National Wildlife Refuge. In areas of steep rocky cliffs, a greater percentage of pellets are expected to enter the marine environment (Cuthbert *et al*, 2014). Once on the sea floor, and prior to disintegration, there is a short period of time in which fish may ingest bait particles. However, some studies have reported that fish or other marine life did not take an interest in the bait (Howald et al, 2015), while a field trial of non-toxic cereal baits (i.e., no pesticide in the formulation) observed two species of fish eating the bait (Empson and Miskelly, 1999).

The community of LHI have identified that some utilise the surrounding fish population for their diet and to support tourism activities (**Appendix D**). Fish species such as garfish, trevally and bluefish are regularly caught by residents for consumption purposes. Though the numbers of fish that could ingest baits and the potential for these individuals to be caught and used for food is expected to be low, the potential health risks associated with the ingestion of fish tissue will be assessed quantitatively in this HHRA.

It is understood that mussels and other shellfish suitable as a food source are either not present in the surrounding marine community (LHIB, 2016), or not readily consumed by residents and visitors to LHI. Therefore, the potential health risks due to the consumption of seafood will focus on the ingestion of locally caught fish.

4.4.3.6 Exposure via Ingestion of Tank Water and Groundwater

The majority of residents and tourist lodges obtain their drinking water via the capture of rainwater on roof surfaces that is stored in large tanks (refer to **Section 2.13** and **Section 2.14**). While filtration of tank water is common, particularly for the tourist lodges, it is understood that rainwater may not be filtered by all residents and tourist lodges.

While exclusion zones around buildings are incorporated into the REP, there is some possibility that a pellet or pellet dust will be unintentionally deposited onto a roof surface during aerial distribution via helicopters. There is therefore a potential for brodifacoum to enter drinking water supplies should the pellet and/or dust be washed from the roof and into the rainwater tank. Furthermore, LHIB (2016) reported that in baiting trials on the island, it was found that some birds consumed the pellets, and therefore their droppings have the potential to contain brodifacoum which may land on roof surfaces and wash into the rainwater tanks. Therefore, the potential for health risks associated with this exposure pathway will be further assessed.

Information from the LHI community indicates that in periods of low rainfall, some residents have historically consumed groundwater for potable drinking purposes even though the high salinity (refer to **Table 2** and **Section 2.13**) suggests that it will be unpalatable. LHIB (2016) states that "*several of the properties have desalination plants for treatment of groundwater before use*", however it is not known how many properties utilise this treatment and whether they use the desalinated groundwater as their drinking water source. Furthermore, it is understood that in more recent times, the LHIB supplements resident's drinking water supplies when their rainwater tank supplies are low, and so use of untreated groundwater as a potable supply after the REP is extremely unlikely. However, as a protective approach, the potential health risks associated with the ingestion of groundwater will be considered further in this HHRA.

4.4.3.7 Exposure via Direct Contact of Groundwater/Surface water

LHI has three main streams and a number of ephemeral streams (refer to **Section 2.10**). Residents and visitors to LHI are known to enter these surface water bodies for recreational purposes, and have been known to drink water from the streams particularly when hiking up Mount Gower (LHIB, 2016). There is a small potential for brodifacoum to enter groundwater (via leaching from soil) and surface water (from surface water runoff and groundwater recharge) where human receptors can be exposed during wading/swimming activities. Potential health risks associated with this exposure scenario will therefore be assessed further in this HHRA.

4.4.3.8 Exposure via Direct Contact with Sediment

Brodifacoum is poorly soluble in water and will tightly bind to organic matter and settle out in creek and beach sediments (sand). As discussed in **Section 4.4.3.7**, residents and visitors to the island are known to enter the freshwater streams and therefore there is a potential for these receptors to come into direct contact with brodifacoum bound to sediment (sand). Potential health risks associated with this exposure scenario will therefore be assessed further in this HHRA.

4.4.3.9 Exposure via Direct Ingestion of the Pestoff 20R Pellets

As discussed in **Section 4.4.1.1**, the majority Pestoff 20R pellets are likely to represent a soft and mushy form within 48 hours of placement on the open ground which would limit the ability of a child to pick up the pellet and intentionally ingest it. However, there is the potential for a pellet to be placed in an area with greater canopy cover which would reduce the pellet’s degradation rate and potential. Furthermore, open bait trays are proposed to be placed within houses (refer to **Section 1.1.2**) in inaccessible areas (e.g., behind refrigerators) where there is a potential (albeit low) for a child to find the tray and ingest a pellet.

Therefore, as a conservative approach this HHRA will assess the potential health risk associated with the direct ingestion of the Pestoff 20R pellets.

4.4.3.10 Exposure via Dermal Contact with the Pestoff 20R Pellets

The Pestoff 20R pellets will be placed onto the open ground within the settlement and forested areas, and any human receptor passing through this area has the potential to have direct contact with the pellet via dermal contact with the skin.

This is particularly relevant for toddlers and school children who were observed to travel across the island without shoes, and for mountain hikers who may unintentionally place their hand on a pellet during mountain hikes. Therefore dermal contact with the Pestoff 20R pellet from the hands and feet will be assessed in this HHRA.

4.4.3.11 Exposure via Pets

As identified in **Section 3.3**, this HHRA does not assess the potential risks of the proposed REP to the health of resident’s pets on LHI. However, pets have the potential to walk through, and lie on, soil that has brodifacoum residue concentrations, and track this soil into a house and/or transfer this soil onto a resident. A pet may also chew on a pellet or eat soil, and then lick a resident. The amount of soil associated with this exposure scenario is much less than that experienced via the incidental ingestion and dermal contact with soil that is being assessed in the HHRA. Therefore, the exposure to brodifacoum via pets will not be quantitatively assessed further in this HHRA, but the potential for such exposures is accounted for by virtue of assuming ingestion of soil that has been directly beneath a bait pellet.

4.4.4 Conceptual Site Model Summary

A summary of the source-pathway-receptor linkages that are quantitatively assessed further in this HHRA is provided in **Table 4.**

Table 4 Conceptual Site Model Summary

Exposure Pathway	Toddler	School Child	Pregnant Female	Adult
Incidental ingestion and dermal contact with soil beneath/adjacent to a degraded pellet	√	√	√	√
Outdoor inhalation of dust derived from pellet during aerial and hand broadcasting distribution	√	√	√	√
Ingestion of locally caught seafood	√	√	√	√
Ingestion of locally grown vegetables and fruit	√	√	√	√
Ingestion of meat, dairy and poultry products	X	X	X	X
Ingestion of tank water/groundwater as drinking water	√	√	√	√
Direct contact and incidental ingestion of surface water	√	√	√	√
Direct contact and incidental ingestion of creek sediment	√	√	√	√
Direct ingestion of Pestoff 20R pellet	√	√	√	√
Dermal contact with Pestoff 20R pellet	√	√	√	√
Exposure via pets	X	X	X	X

√ indicates that exposure pathway is quantitatively assessed in the HHRA

X indicates that a complete SPR-linkage is not present, and therefore is not quantitatively assessed in the HHRA

5. HAZARD ASSESSMENT

Hazard assessment is typically divided into two stages: hazard identification; and dose-response assessment. The hazard identification stage is a qualitative description of the capacity of a contaminant or agent to cause harm. The dose-response assessment includes the selection of appropriate toxicity criteria following a review of published and reliable sources.

5.1 Brodifacoum Hazard Identification

The hazard identification process provides a means in which to consider the capacity of a specific agent to produce adverse health or environmental effects. Hazard identification comprises the initial part of the toxicity assessment process involving the consideration of the types of adverse health effects that might be caused by a given agent and uncertainty analysis of toxicological data.

The current hazard assessment is based on a recent safety evaluation performed in the context of active substance approval under the European Biocidal Products Regulation No. 528/2012 – the "BPR" (EU Assessment Report, 2010) supplemented by a corresponding opinion issued by the European Chemicals Agency (ECHA) Biocidal Products Committee (BPC) (ECHA, 2014). The European review of hazards of brodifacoum as a rodenticide is a comprehensive evaluation of available information for this substance and specifically addresses both the established anticoagulant effects of brodifacoum and the basis for applying read-across information from warfarin with regard to accounting for hazards relating to teratogenic effects during development. This evaluation was reviewed and presented by human health and environmental experts from the authorities of 27 (at the date of finalisation) EU member states, peer-reviewed and approved by the Biocides Technical Meeting. This review process resulted in inclusion of brodifacoum into Annex I of the Biocidal Products Directive 98/8/EC (i.e. approval of the active substance), as implemented by the amending Commission Directive 2010/10/EU.

The current risk assessment and hazard identification in the context of the proposed rodent eradication on Lord Howe Island shall consider most recent information on the hazards of the active substance brodifacoum, in combination with potential exposure under protective assumptions, resulting in characterisation of the possible risks to residents and visitors to the island.

5.1.1 Physical and Chemical Properties of Pestoff 20R and Brodifacoum

The physical and chemical properties of brodifacoum are presented **Table 5**.

Table 5 Physical and Chemical Properties of Brodifacoum

Variable	Symbol	Unit	Value	Source
CAS Number	-	-	56073-10-0	CLH, 2013
Chemical Formula		-	$C_{31}H_{23}BrO_3$	CLH, 2013
Molecular Weight	MW	g/mole	523.4	CLH, 2013
Henry's Law Constant @ 25°C	H'	atm-m³-mol	2.2×10^{-8}	CLH, 2013
Vapour pressure @25°C	P	mmHg	3.0×10^{-7}	CLH, 2013
Aqueous Solubility @20°C	S	mg/L	0.24	CLH, 2013

Variable	Symbol	Unit	Value	Source
Soil-water partition coefficient	Kd	cm^3/g	Not determinable, due to slow desorption	EU Assessment Report, 2010
Half-life in soil	-	days	157	EU Assessment Report, 2010
Organic carbon partition coefficient	Koc	cm^3/g	9155	EU Assessment Report, 2010
Log of octanol-water partition coefficient	log Kow	-	6.2	Based on measured Koc values (ECA, 2013)[1].
Gastrointestinal absorption	GIA	-	75%	EU Assessment Report, 2010
Dermal absorption factor	DAF	-	0.05	EU Assessment Report, 2010
Dermal permeability	Kp	cm/hr	0.03	Calculated using MW and logKow (US EPA, 2003).
Diffusivity in air	Dair	cm^2/sec	0.0368	Calculated using US EPA Online Tool (Updated Feb 2016)[b]
Diffusivity in water	Dwater	cm^2/sec	3.35×10^{-6}	
Aquatic bio concentration factor	BCF	-	35134	Calculated using log Kow of 6.12 (EU Assessment Report, 2010)

Notes:

a) Two $\log_{Kow}$ values are provided in EU Assessment Report (2010) and the authors considered that the value of 6.12 is the most appropriate value since it is based on measured Koc values which gives more confidence than the estimates based on structural formula that resulted in a in a $\log_{Kow}$ of 8.5.

b) US EPA On-line Tools for Site Assessment calculation last updated 24 February 2016 available at: https://www3.epa.gov/ceampubl/learn2model/part-two/onsite/estdiffusion-ext.html

5.1.2 Environmental Fate and Transport

The information in this section is adopted from the EU Assessment Report (2010) issued in the context of evaluation of the substance under the European BPD/BPR.

Adsorption of brodifacoum onto soil, sediment, or sewage sludge is dependent on pH. At neutral and acidic conditions, the substance adsorbs strongly to soil and is minimally transferred to water, resulting in an average soil adsorption coefficient Koc values of 9155 L/kg. In other words, the amount of brodifacoum adsorbed onto the solid soil matrix is, on average, approximately a factor 10 000 higher than the amount dissolved in soil pore water. The solubility of brodifacoum slightly increases at pH levels greater than 9, however highly alkaline soil conditions would be unusual and are not expected to be relevant for LHI. Soil pH between 5 and 9 have been reported on LHI from studies conducted on the Mt Gower plateau (Pickard (1983) and in areas of palm vegetation (Savolainen *et al*, 2006). Solubility reduces exponentially with decreasing pH. Soil pH conditions between neutral and 9 fall within the range of brodifacoum insolubility with water (WHO 1995, USEPA 1998). The EU Assessment Report draws the conclusion that brodifacoum is immobile in soil hence not expected to be transported to groundwater substantially. Recognising that this is the best currently available scientific characterisation of expected situation for soil-to-groundwater transfer, for the purposes of the HHRA, transport to groundwater was predicted using a model (see **Section 4.4.3.6** and **Section 6.1.5**) in order to be able to quantitatively address in a protective manner concerns expressed by the community about exposure to groundwater subsequent to bait distributions.

5.1.3 Persistence and Bioaccumulation

5.1.3.1 Degradation and Persistence

In screening biodegradability tests, brodifacoum biodegrades relatively slowly. Brodifacoum can be broken down by soil microorganisms to its base components, carbon dioxide and water; and the bromine gas is expected to volatilise to the atmosphere.

Brodifacoum is stable to hydrolysis (breakdown in water or moisture in soil). In soil, brodifacoum is biologically degraded with a half-life of 157 days at 20 °C (EU Assessment Report (2010)). However, when exposed directly sunlight and UV radiation, the active substances undergoes photolytic degradation relatively quickly, with a range of environmental half-lives between 23 minutes (summer) and 366 minutes (winter) (FAO/WHO, 2014).

5.1.3.2 Bioaccumulation

Experimental data on aquatic and terrestrial bioconcentration are not available. Therefore, the assessment of the bioaccumulation potential of brodifacoum has to rely on theoretical considerations.

Bioaccumulation as a passive distribution process between aqueous and fatty phases may be evaluated on the basis of the partitioning coefficient (log P_{ow}).

Furthermore, bioaccumulation of coumarin-derived anticoagulants like brodifacoum needs to be considered in the light of target organs where is tends to localise. In the liver of vertebrate animals, brodifacoum binds to the membrane-bound enzyme vitamin K epoxide reductase (VKOR). Due to the lipophilicity of brodifacoum, this binding is strong and the substance is only slowly eliminated from the liver. Accordingly, brodifacoum tends to accumulate in the liver of vertebrates. A quantitative measure of this bioaccumulation process in terrestrial vertebrate liver is not available, but it is to be expected that a worst-case aquatic bioaccumulation factor (BCF) scenario will be protective and this is assumed for the HHRA.

5.1.4 Toxicokinetics

Upon ingestion, approximately 75 % of a brodifacoum dose is absorbed in the gastrointestinal tract. The substance is widely distributed in the body, with the highest proportion retained in the liver (22.8 %), followed by the pancreas (2.3 %), kidneys (0.8 %), heart (0.1 %) and spleen (0.2 %). The remainder of the dose (ca. 50%) is distributed in muscle, fat and skin based on rat studies (EU Assessment Report, 2010).

Brodifacoum is slowly and partially metabolised: 31.3 % of the whole body residue in a rat study, and 19.6 % of the residues in liver were unchanged brodifacoum. Metabolites were identified as glucuronides of the parent compound. Brodifacoum is slowly eliminated from the body, both as unchanged parent compound and glucuronides. The main elimination pathway is via the bile and the faeces. Elimination follows a bi-phasic pattern with a rapid first phase (for up to 4 days after administration), and a slow terminal phase. Depending on the dosing regime (single or repeated dose) the overall elimination half-life varies between 128 and 200 days. Elimination from the liver may take even longer, with a half-life of 282–350 days (EU Assessment Report, 2010).

Dermal absorption of brodifacoum from rodenticide formulations (pellet bait) was measured in an in vitro skin penetration study. An absorption rate could not be determined since absorbed amounts were less than the limit of quantitation of the analytical method (1.64–3.53 % of the applied dose). Therefore, the EU regulators adopted a worst-case surrogate dermal absorption value of 5 %.

For inhalation exposure, it is protective to assume 100 % absorption.

5.1.5 Threshold (non-carcinogenic) Health Effects

5.1.5.1 Acute Health Effects

In animal experiments, brodifacoum was very toxic to rats and mice with oral LD50 values of approximately 0.4 mg/kg bw in male rats and mice. Brodifacoum is also acutely toxic by the dermal and inhalation routes (LD50, dermal = 3.16 mg/kg bw; LC50, inhalation = 3.05 mg/m^3). Death was the result of internal haemorrhage related to the anticoagulant effects understood as the mechanism of action for this substance.

Clinical reports of human poisoning incidents showed increased bleeding tendency, which include the following:

- "*Minor poisoning: coagulation disturbance detected only by laboratory analyses;*
- *Moderate poisoning: coagulation disturbance resulting in haematomata, haematuria, blood in faeces or excessive bleeding from minor cuts or abrasions, gum bleeding; and*
- *Severe poisoning: retroperitoneal haemorrhage, severe gastrointestinal bleeding, cerebrovascular accidents, massive haemorrhage (internal bleeding) resulting in shock*" (WHO, 1995b).

For many of the reported human poisoning incidents dose information is not available, or the incident involved a massive (typically intentional) dose well above the lowest threshold for the most sensitive effects. There are numerous case reports of adults experiencing serious or fatal outcomes from brodifacoum, however the amounts of rodenticide bait involved, where known, are typically listed in terms of the numbers of boxes of bait consumed and involve an intent to self-harm (HSDB, 2016),

The World Health Organisation (WHO) and the U.S. Environmental Protection Agency (USEPA) has specified that a dose of 1 mg of brodifacoum for an adult is the minimum level at which anticoagulant effects have been recognised (WHO, 1995a; USEPA, 2013). This threshold is based on a case report of an adult experiencing anticoagulant effects after ingesting approximately a mouthful of a liquid form, calculated to contain approximately 1 mg of brodifacoum (Smolinske *et al*., 1989; Chen and Deng, 1986). This amount corresponds to approximately ½ packet of Talon (50 ppm brodifacoum) bait or 25 pellets of Pestoff 20R bait (10 mm diameter size, 20 ppm brodifacoum). The lowest reported dose of brodifacoum noted to produce anticoagulant effects after consumption of rodenticide pellets is 7.5 mg by an adult (Jones *et al*., 1984).

Evaluating cases of brodifacoum ingestion by children reported to a poison control centre, Smolinske and co-workers (1989) noted that 7 out of 77 (9%) exhibited abnormal prothrombin time results, indicating observable anticoagulant effects. The amount of documented exposure ranged from "a taste" to "½ to 1 pack" of bait for children exhibiting anticoagulant effects, however in more than half of these cases, the amount ingested was unknown. The authors note that for these cases, the abnormal prothrombin time results "usually resolved within 72 hours" (p. 494, Smolinske *et al*., 1989).

A larger study evaluated cases of brodifacoum exposures reported to a nationwide association of poison control centres in the US (Shepard *et al*., 2002). A total of 10,762 reported cases involving children under age 7 were reviewed and anticoagulant effects were found in 67 cases, classified as "minor" for 38 cases and "moderate" for 54 cases. No major effects or fatalities were found (Shepard *et al*., 2002).

The contrast between the well documented anticoagulant effects including fatalities in case reports involving adults and the relatively uncommon occurrence of any clinical effects in the cases involving children likely reflects the difference between exploratory versus intentionally self-harmful behaviour. The amounts of bait ingested during exploratory behaviour are generally constrained by the amount immediately and incidentally accessible to a child. However, adults acting with intent to self-harm are motivated to seek out and then open multiple packaged units of baits. With regard to the HHRA, the former type of exposure is more relevant. Children (or adults) may encounter individual bait pellets that have been distributed and exploratory behaviour exposure scenario is considered.

5.1.5.2 Chronic Health Effects

Repeated dose oral studies show that in the rat and in the dog, the clinical signs, haematological and post mortem data were consistent with the known pharmacological action of brodifacoum: impairment of the clotting cascade and increased prevalence of haemorrhage leading to death (EU Assessment Report, 2010). There were no indications of secondary toxicities. None of the other study parameters (histopathological analysis, biochemistry, haematology, or urinalysis) revealed any treatment related alterations. The lowest (i.e., most critical) no-observed effect level (NOEL) was identified in a subchronic 90-day oral toxicity in rats. In this type of study, the test substance is ingested daily over 90 days, serving as a subchronic repeated dose. The repeated-dose toxicity NOEL was determined at 0.001 mg/kg bw/day. Identification of the NOEL was based on statistically significant increases of kaolin-cephalin time (KCT) and prothrombin time (PT), measurements of anti-coagulant effects on the blood, at the highest dose level (0.004 mg/kg bw/day) after 90 days. No other toxic effects were observed, which supports identifying anticoagulant or haemorrhagic effects as the most sensitive adverse response to brodifacoum. No adverse effects were observed at the next lower dose of 0.001 mg/kg bw/day. (EU Assessment Report, 2010). When testing of this type finds both a dose at which effects occur and lower doses at which the same effects are not seen, there is a clear basis to establish that a threshold dose needed to produce the effect has been found and that the next lower dose is a protective level at which no adverse effects are expected. This is the NOEL that serves as the starting point for deriving values used in HHRA. (For calculation of NOEL in humans see **Section 5.2.1**).

Chronic carcinogenicity studies in animals are not available. Performance of such studies was considered unnecessary in view of interference with the blood clotting system (and potentially teratogenicity, see below) being the only toxicologically relevant effects. Furthermore, brodifacoum was tested negative in a complete battery of in vitro genotoxicity tests. Therefore, there are no indications of a mutagenicity based carcinogenic mechanism. The EU Assessment concluded that brodifacoum is not carcinogenic (EU Assessment Report, 2010).

Brodifacoum is not suspected to show any endocrine activity. There were no indications of neurotoxicity in any of the studies. Furthermore, there were no signs of immunotoxicity (EU Assessment Report 2010).

5.1.6 Potential Impacts on Sensitive Sub-groups

5.1.6.1 Pregnant Women (and the Developing Foetus)

The EU evaluation concluded that the testing results for brodifacoum did not show teratogenic effects on developing offspring, stating “no foetal toxicity was observed in the developmental toxicity studies with brodifacoum” (EU Assessment Report, 2010, p. 10). The recognised haemorrhagic effects of brodifacoum were the most sensitive effects and the mothers and developing offspring experienced impacts from these anticoagulant mechanisms during testing.

Three case reports involving pregnant women exposed to brodifacoum where effects on the foetus also occurred were reviewed by the EU. In all cases, both the mother and the foetus experienced haemorrhagic effects related to the anticoagulant mechanism of brodifacoum (EU Assessment Report, 2010). There were no teratogenic effects similar to those documented for warfarin (discussed below) in these cases. And, there are no other case reports of human foetuses demonstrating teratogenic effects subsequent to brodifacoum exposure by the mother.

Since teratogenic effects were not produced at the doses sufficient to cause substantial toxicity via haemorrhage, the anticoagulant effects are demonstrated by the available testing results to be the most sensitive endpoint. However, based on the availability of information that the similar anticoagulant warfarin can induce teratogenic effects at more sensitive dose levels than its haemorrhagic effects, the EU also concluded that read-across of the information relating to warfarin should be applied to brodifacoum and that brodifacoum should be characterised on the basis of potentially having teratogenic properties (EU Assessment Report, 2010; ECHA, 2014).

Hydroxycoumarin anticoagulants, including brodifacoum and warfarin, share a common mode of action: competitive inhibition of the enzyme vitamin K epoxide reductase – VKOR – thereby preventing reduction of vitamin K epoxide to fully functional vitamin K1. Accordingly, the vitamin K1 stored in the body is depleted and vitamin K dependent physiological processes are disrupted. A commonality of these processes is that vitamin K provides energy and reduction equivalents for carboxylation of glutamyl side chains of some physiologically important proteins. Among these vitamin K-dependent proteins are the blood clotting factors II, VII, IX and X, which is why hydroxycoumarins are potent anticoagulants.

Additional proteins that are carboxylated with the help of vitamin K are osteocalcin, matrix Gla protein (MGP), periostin, and Gla-rich protein (GRP). All of these proteins play an important role in bone metabolism and formation, particularly in developing bone in the foetus. Accordingly, VKOR is also located in bone tissue, in order to enable formation of the aforementioned proteins. In case a hydroxycoumarin anticoagulant reaches foetal developing bone in sufficient amounts to block the VKOR protein formation, bone development will be disturbed which may result in malformations known as foetal warfarin syndrome. Hypoplasia of the nasal bridge, stippled epiphyses, and growth retardation are the most significant symptoms. These malformations are invariably associated with warfarin medication (anticoagulant treatment e.g., due to artificial heart valves, amongst other indications) of pregnant women, i.e. the patients received doses at a level intended for interfering with their blood clotting system. There are no indications of foetal warfarin syndrome occurring when warfarin exposure of the mother is below the threshold for producing anticoagulant effects. In other words, even for warfarin, the anticoagulant effects are the more sensitive endpoint and teratogenic effects are not expected in the absence of anticoagulant effects in the mother.

The common mode of action of the hydroxycoumarin anticoagulants was used as the essential argument by European risk assessment bodies to extrapolate the teratogenic potential from warfarin to all other chemically related anticoagulants (read-across). Warfarin is classified as a category 1A reproductive toxicant, since teratogenic effects have been demonstrated in humans. In a classification proposal, adopted by the European Risk Assessment Committee (RAC) on 14 March 2014, the reproductive toxicity classification of warfarin was transferred one-to-one to brodifacoum, i.e. the substance is proposed to be classified as if there were malformations that could directly be attributed to brodifacoum exposure of pregnant women (ECHA, 2014). The implementation of this classification proposal is currently still pending.

The European authorities responsible for assessing the risks of and for approving biocidal active substances took the possible teratogenicity of brodifacoum when developing acceptable exposure levels (EU Assessment Report, 2010). In addition to the standard assessment factors (AF) for extrapolating the effects seen in animal studies to humans, a further AF of 3 was applied which accounted for the “severity of effects”, i.e. impact of malformations on affected persons. Applying an additional AF, i.e. increasing the margin of safety by this value has been generally agreed upon by the European competent authorities for biocides. This can be considered as a clear worst-case approach in view of the lack of direct evidence for the suspected teratogenic potential of brodifacoum.

In the HHRA, the EU-specified value treating brodifacoum as potentially teratogenic and adjusting for this effect in the derivation of the toxicity value is adopted. The acceptable exposure levels reported in **Section 5.2.1** adequately considered the potential effects that may arise from assumed teratogenicity and is therefore considered sufficiently protective with respect to pregnant women.

Potential effects of brodifacoum via lactation have to date not been identified as a concern. In view of the fact that brodifacoum accumulates mainly in the liver, and is predominantly excreted via faeces, lactation is not considered to be a significant elimination pathway. The acceptable exposure levels reported in **Section 5.2.1** below can be considered to be sufficiently protective with respect to breastfeeding women and their babies.

5.1.6.2 Children and Elderly People

The standard assessment factor, as applied by European competent authorities, for extrapolating from no-observed effect levels in animal studies to safe exposure levels for humans, is designed to take into account a considerable degree of variability of individuals and sub-populations, as explained in detail in **Section 5.2.1**. Accordingly, the potentially different sensitivity of children and elderly can be considered to be adequately reflected by the acceptable exposure level (AEL), which is therefore regarded as sufficiently protective.

5.1.6.3 Persons Taking Warfarin Therapeutically

Patients with coagulation disorders may be treated with warfarin in order to prevent uncontrolled and excessive blood clotting. Therefore they are administered warfarin doses aimed at maintaining a normal blood clotting regime. In addition, patients with certain cardiovascular conditions may be administered warfarin specifically to achieve therapeutic lowering of blood clotting potential. Patients taking warfarin are at a higher risk of haemorrhaging than untreated persons. Higher susceptibility of warfarin treated patients to potential brodifacoum exposure would thus seem plausible.

The mode of action and the site of action of warfarin and brodifacoum are the same: inhibition of VKOR, thereby depleting the stocks of active vitamin K1. A recent literature search revealed no hits when looking for interactions between warfarin therapy and brodifacoum, which is not unexpected since brodifacoum is not used for therapeutic purposes, hence co-administration does not occur routinely.

Actual risks of warfarin patients, however, cannot be quantified. It is noteworthy that brodifacoum shows a considerably higher binding affinity to VKOR than warfarin (Ferencz and Mutean, 2015; Londhe and Chabukswar, 2015), and is metabolised much slower. Therefore based on this information, it could be expected that, in case of brodifacoum exposure of warfarin-treated patients, brodifacoum would readily displace warfarin from the VKOR due to its higher reactivity. This would mean that rather than having an additive effect, brodifacoum would tend to substitute for and replace the intended warfarin effects.

Interactions are known for the non-steroidal anti-inflammatory drugs (NSAIDs) ibuprofen and phenylbutazone. These drugs are reported to potentiate the anticoagulant effects of brodifacoum and bromadiolone in rats in both field and laboratory trials where the drugs reportedly reduced the lethal dose required for 100% mortality as well as days to death (Sridhara and Krishnamurthy, 1992). The interaction mechanisms of these drugs includes altering the absorption, binding and/or metabolism of protein. NSAIDs can cause gastrointestinal damage via ulceration and bleeding, and can interfere with the wound healing process; thereby enhancing the efficacy of brodifacoum by affecting their binding, inducing gastric ulceration, bleeding and finally by interfering with the natural healing of wounds (Sridhara and Kirshnamurthy, 1992). Since this interaction occurs in conjunction with exposures significant enough to produce clinical signs of poisoning, it is a matter of note that patients on warfarin therapy, where anticoagulant effects are actually induced, may wish to discuss with their treating medical professionals. Drug interactions are not addressed directly in the HHRA more generally as the comparisons made for this analysis relate to much lower “no-effect” levels and the uncertainty factors incorporated to account for sensitive individuals account for this type of potential sensitivity.

5.2 Dose-Response Assessment

As a consequence of accumulation in the liver and slow elimination from the body, the dose-response curve of brodifacoum can be relatively steep. As discussed above (**Section 5.1.5.2**), both a NOEL (0.001 mg/kg/d and a lowest observed effect level (LOEL) of 0.004 mg/kg/day were noted from the same 90-day rat study. The factor of 4 difference between these values suggests that relatively small increases in dose can begin to initiate effects. A factor of 10 difference between a NOEL and LOEL is typical for many chemicals. In addition to the results from the rat study, a NOEL was also determined from repeated dose testing in another species – dogs. Dogs were dosed daily via ingestion for 6 weeks and a NOEL of 0.003 mg/kg/day and a LOEL of 0.01 mg/kg/day for anticoagulant effects were determined. Since this study included a shorter dosing period and the NOEL was higher than found in the rat study, it is used to demonstrate the consistency of the nature of the effects and dose-response characteristics, but is not selected as the basis for the HHRA. Use of the results from the rat study is more protective.

In summary, repeated-dose toxicity studies that allow for unequivocal identification of a no-observed effect level (NOEL) are available. Accordingly, a dose could be identified in animal studies at and below which no adverse health effects need to be expected.

5.2.1 Adopted Dose-Response Values

As already elaborated in **Section 5.1.5.2,** a NOEL of 0.001 mg/kg bw/d has been identified in a 90-day oral toxicity study in rats. Deriving safe exposure levels for humans involves a number of factors which are eventually summed up to an overall assessment factor by which the NOEL is divided. The discrete parts of the overall assessment factor are specified as follows (ECHA, 2015):

- Interspecies differences (the possibility that humans are more sensitive than the test animals, based on differences in body weight, toxicokinetics, metabolism): default factor 10.
- Intraspecies differences (variability across various sub-groups, e.g. children, elderly people, differences by sex, health status, nutritional status, individual metabolic differences, etc.): default factor 10.
- Exposure duration: Depending on the duration of the toxicity study and the assumed exposure duration of the assessed human population. In the current case, the underlying toxicological study was a 90 day study in rats. The life periods of rat and humans can be compared as follows: 26.7 human days = 1 rat day (Sengupta, 2013). The study duration thus corresponds to 2403 human days or approximately 6.5 years. In view of the length of the planned baiting period, also considering potential prolonged oral exposure via the environment due to residues, it would not appear necessary to extrapolate the exposure duration. A factor of 1 can be considered as appropriate.
- Dose-response relationship: In the current case, a NOEL is the reference endpoint for identifying safe exposure levels, i.e. no effects were observed in the animal study: default factor 1.
- Quality of the data base: The toxicity studies upon which e.g. the EU risk assessment for brodifacoum is based were performed according to pertinent OECD test guidelines in compliance with Good Laboratory Practice (GLP), and the data set was assessed as sufficiently complete for hazard assessment: default factor 1.

An initial assessment factor of 100 is therefore derived to be protective for all potentially exposed standard sub-groups, since differential sensitivity by sex, age, genetic characteristics, health status, etc., are taken into consideration. Furthermore, the European authorities have applied an additional AF of 3, accounting for the severity of toxic effects related to the potential teratogenicity of hydroxycoumarin anticoagulants as a group. This worst-case scenario approach has been adopted for assessing the potential human health risks of the planned Pestoff 20R baiting on Lord Howe Island.

The sub-chronic AEL developed by the EU is considered adequate with respect to exposure duration, as explained above. The AEL is a systemic reference dose (RfD), i.e., it integrates exposures via all possible pathways (oral, dermal, inhalation). The exposure assessment will therefore integrate estimated worst-case exposures from all identified sources (total systemic exposure), and then compare them with the RfD.

A separate reference concentration (RfC) for inhalation (e.g. of particles) can be derived from the AEL by considering the time-specific breathing volume of 20 m^3/day and a body weight of 70kg for the assessed population, using the following formula:

$$RfC\left[\frac{mg}{m^3}\right] = \frac{AEL\left[\frac{mg}{kg\ bw\ \times d}\right] \times body\ weight\ [kg]}{breathing\ rate\ [\frac{m^3}{d}]}$$

The toxicity dose-response values for brodifacoum adopted for the HHRA represented in **Table 6**. All of these values are based upon the no-adverse-effect level identified by the EU (2010) and specifically adjusted to account for potential teratogenic effects. Thus, the quantitative risk estimates of the HHRA account for this potential effect identified via read-across from warfarin. And, by virtue of being based on the most sensitive potential endpoint, the adopted dose-response values are also protective against any other effects expected to be less sensitive (i.e., require higher doses). In the case of brodifacoum, the established anticoagulant effects are protectively addressed by using the teratogenicity-based value.

Table 6 Adopted Dose-Response Values for Brodifacoum

Chemical	RfD oral (mg/kg/day)	RfD dermal (mg/kg/day)[1]	RfC (mg/m^3)[2]
Brodifacoum	0.0000033	0.0000025	0.000012

Notes:

1) RfD for the dermal pathway derived by multiplying the RfD_{oral} by the fraction of brodifacoum absorbed in the gastrointestinal tract (US EPA, 2004). An absorption factor of 75% was assumed (**Table 5**). [$3.3x10^{-6}$ (mg/kg/day) x 0.75 = 2.5×10^{-6} mg/kg/day]

2) RfC derived by multiplying by a body weight of 70 kg, and dividing by a breathing rate of 20 m^3/day (enHealth, 2012). [($3.3x10^{-6}$ (mg/kg/day) x 70 kg)/ 20 m^3/day = $1.2x10^{-5}$ mg/m^3]

An Australian reference value is also available, namely an acceptable daily intake (ADI). An ADI is, by definition, calculated based on presumed lifetime exposure to chemicals via the diet. The ADI is commonly used in conjunction with pesticide registration where residue on or uptake into food items that could be an ongoing, routine part of diet is to be considered. Considering the length of the baiting period of the proposed rodent eradication programme, and also taking into account potential prolonged exposure from slowly degraded residues (soil half-life = 157 days, see **Section 5.1.3.1**) a value derived for lifetime dietary exposure to brodifacoum is not relevant for the HHRA. Nevertheless, the Australian ADI is reported here for the sake of completeness and comparison purposes:

ADI = 0.0000005 mg/kg bw/d = 5.0×10^{-7} mg/kg bw/d.

5.2.2 Incidental Acute Pellet Ingestion Comparison Value

As discussed above, toxicity reference values for standard HHRA purposes of informing decisions and plans are derived and intended to correspond to dose levels at which no adverse effects are expected for exposed groups, including sensitive subpopulations. Reference values derived in this manner cannot be used to characterise the actual occurrence of potential effects.

However, since the REP relates to a planned future chemical release in which individuals on the island could be directly exposed to rodenticide baits, not just the chemical distributed into environmental media like soil and water, the topic of characterizing the margin of safety in the case where individuals, particularly children, might come in contact with the pellets, have been raised by community members. In this case, the specific issue is what type of exposure to the bait pellets themselves would be necessary to produce actual adverse health effects. This question is readily understood to be of interest to island residents, particularly parents and guardians considering the potential outcome should children consume or play with the bait pellets. This requires a fundamentally different reference value based upon dose levels recognised to produce effects, as opposed to standard no-effect levels.

To evaluate this topic, a supplemental comparison value to be used specifically to characterise the circumstances where effects could result from incidental acute exposure to Pestoff 20R pellets containing 20 mg/kg brodifacoum is derived. This value is not used in the other exposure scenarios addressed in the HHRA because the standard risk assessment approach specified by enHealth guidelines requires the use of predicted no-effect levels where planning or cleanup decisions are being informed by the HHRA. This supplemental value and comparisons using it reflect a case-specific modification versus the enHealth guidelines intended to help inform islanders regarding circumstances and risks relating to possible health effects for individual children in contact with bait pellets.

Because direct ingestion of baits produces a higher dose than dermal contact, the acute risks will be characterised based on the assumed ingestion of bait pellets by children. Other foreseeable direct contact with pellets for children could include stepping on them barefoot, or handling them while playing. But, since consumption of pellets would be more of a potential risk, this scenario is selected as it will provide parents and guardians with context on what would be expected with this “worst-case” incident.

Acute exposure (i.e., one-time incidents) is the relevant scenario for this evaluation since the presence of the green dye included in the pellet formulation for safety purposes can be reasonably relied upon to bring mouthing or ingestion of pellets by a child to the attention of adults.

As described in the hazard assessment (**Section 5.1**), USEPA has considered the topic of identifying a lowest dose level of brodifacoum recognised to produce the sensitive effect for humans, anticoagulant effects. Based on the large database of intentional poisoning events (Shepard *et al*., 2002) and available information on the doses involved, USEPA specifies that 1 mg brodifacoum in a single event for an adult (USEPA, 2013)) can be sufficient to produce toxicity in the form of anticoagulant effects. This dosage is relevant and appropriate to use in addressing concerns relating to individuals consuming pellets.

To consider the corresponding dose for children, the adult dosage must be converted to a dose per unit body weight (this is further converted into number of Pestoff 20R pellets in **Section 7.6**). Using the lighter adult receptor body weight included in the HHRA (66.6 kg female), the lower, (more protective) end of the WHO range corresponds to a dose rate of 0.015 mg/kg bw (1 mg / 66.6 kg). This dose rate is used to calculate a corresponding dosage corresponding to a one-time incident for the child receptors included in the HHRA as follows:

Toddler – (15 kg * 0.015 mg/kg) = 0.23 mg

School Child – (35.6 kg * 0.015 mg/kg = 0.53 mg

These comparison values represent the dosage of brodifacoum that would be expected to represent a threshold at which readily anticoagulant effects that would resolve with monitoring or vitamin K treatment might be expected following accidental ingestion in one day or over a series of days.

5.2.3 Background Exposure

Background levels of chemical exposure comprise chemical concentrations present in the environment as a result of everyday activities or natural sources. These chemicals may be present in food, air, water and consumer products and represent the non-site sources of chemical exposure. This is commonly referred to as background exposure which should be taken into account during the assessment of potential human health risk.

Brodifacoum is a synthetic substance that does not occur naturally. It is only used as a rodenticide in baits. While some residents are understood to use brodifacoum-containing bait