



**Chief Scientist
& Engineer**

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

NSW Chief Scientist & Engineer

July 2017



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**Chief Scientist
& Engineer**

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.

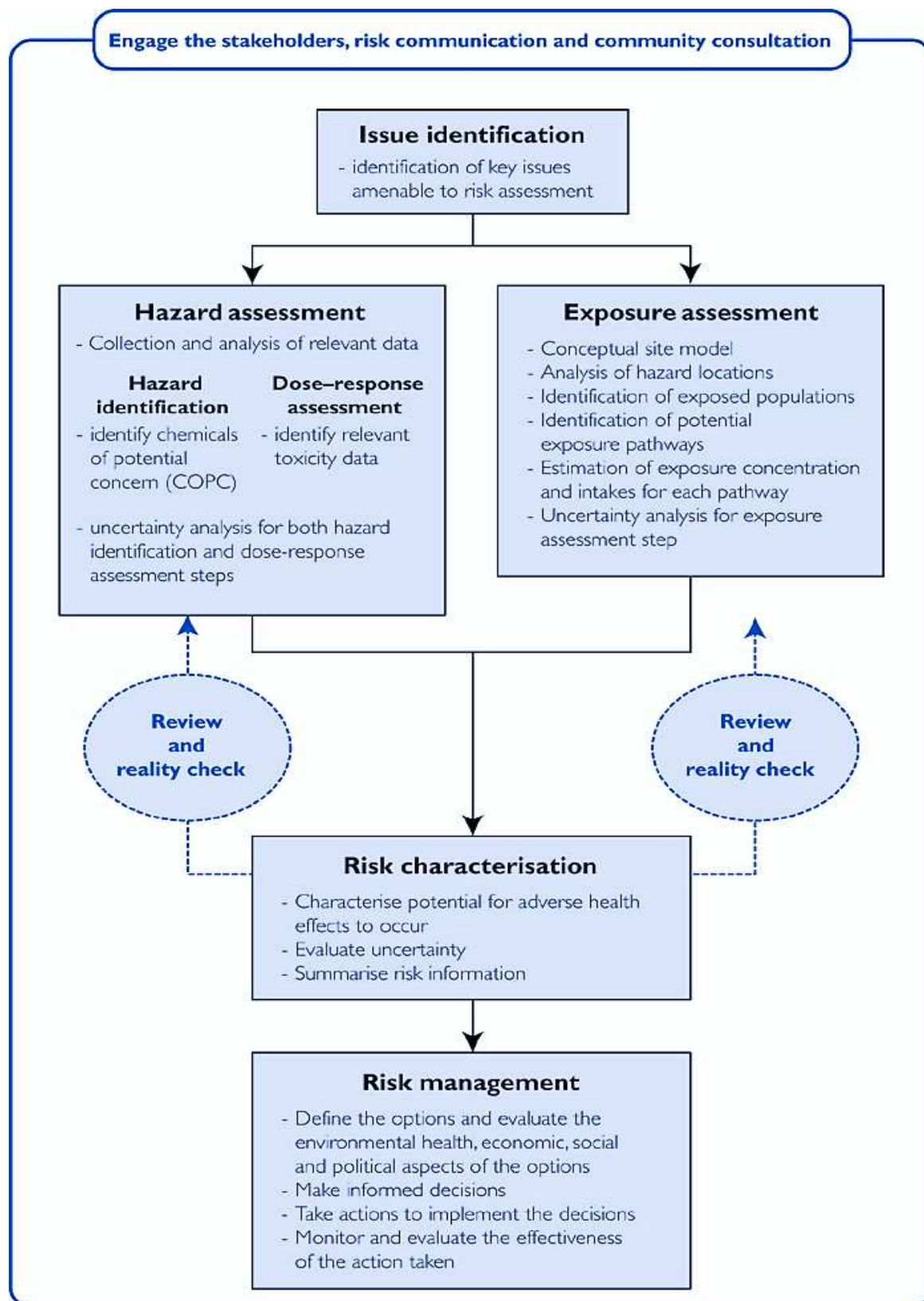


Figure 1: Environment Health Risk Assessment Model¹

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).

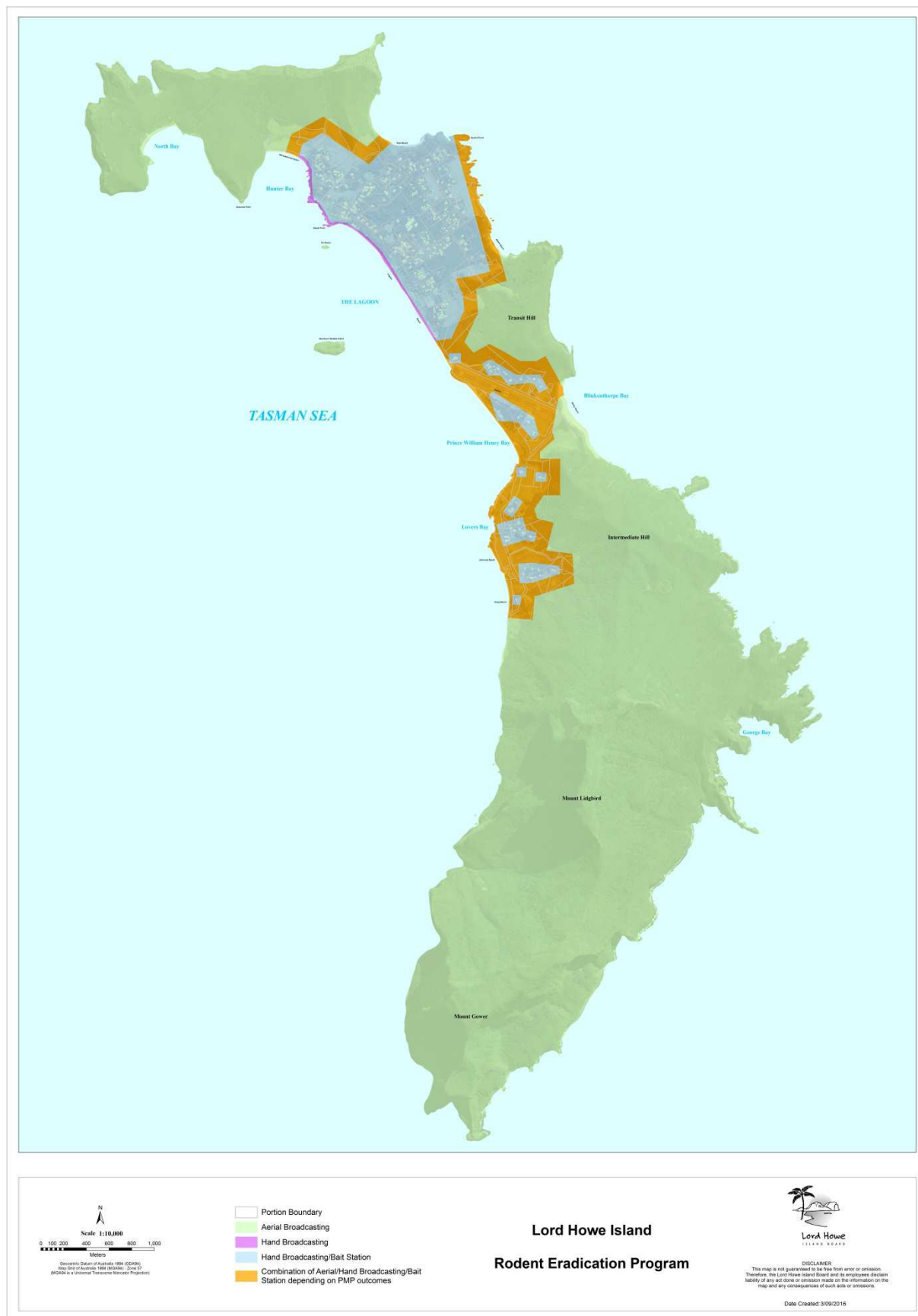


Figure 2: Distribution of Pestoff 20R for the proposed REP – entire island

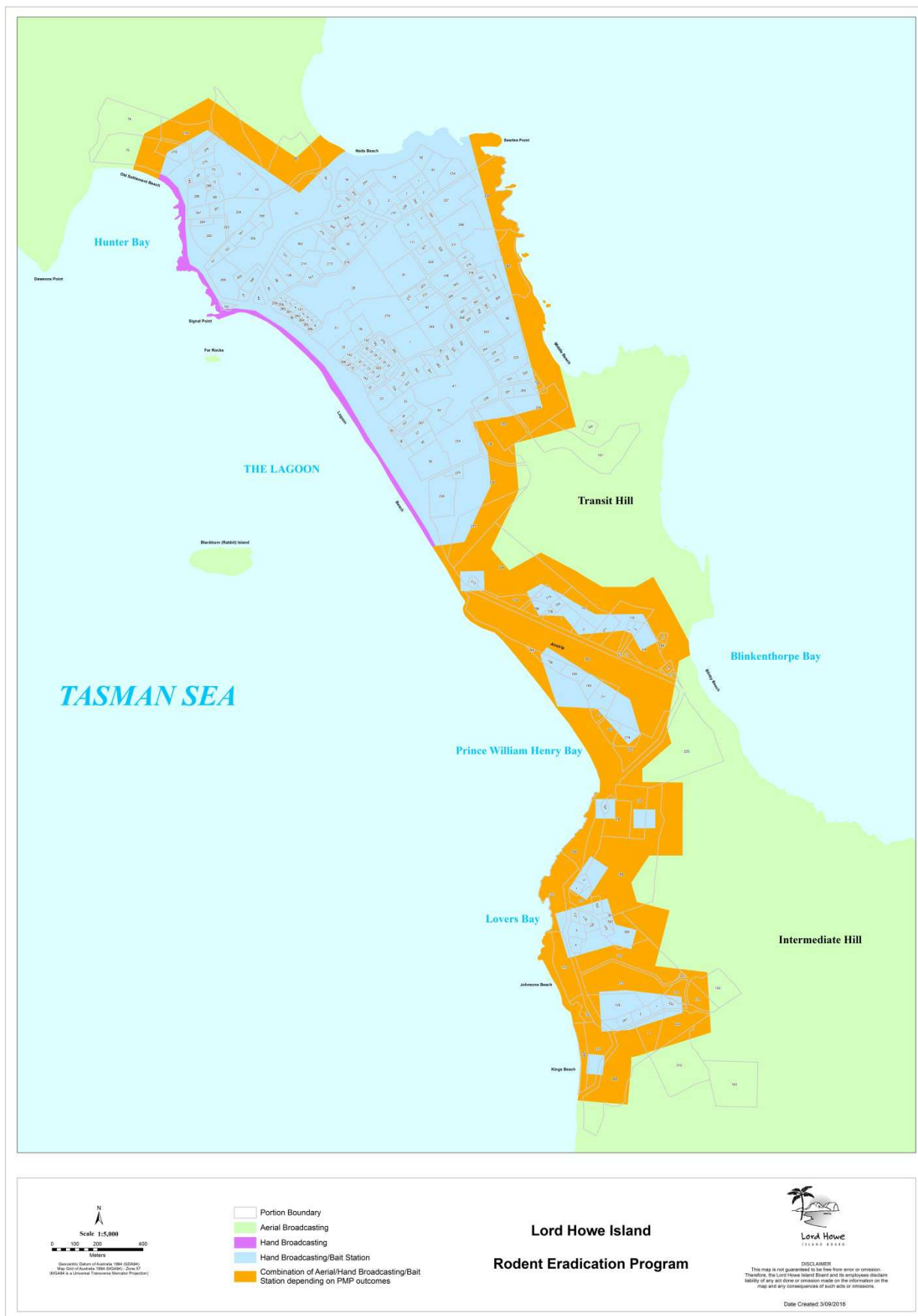


Figure 3: Distribution of Pestoff 20R for the proposed REP – middle of island

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 Committee². 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 included 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 HHRA. 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 contact 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 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

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).

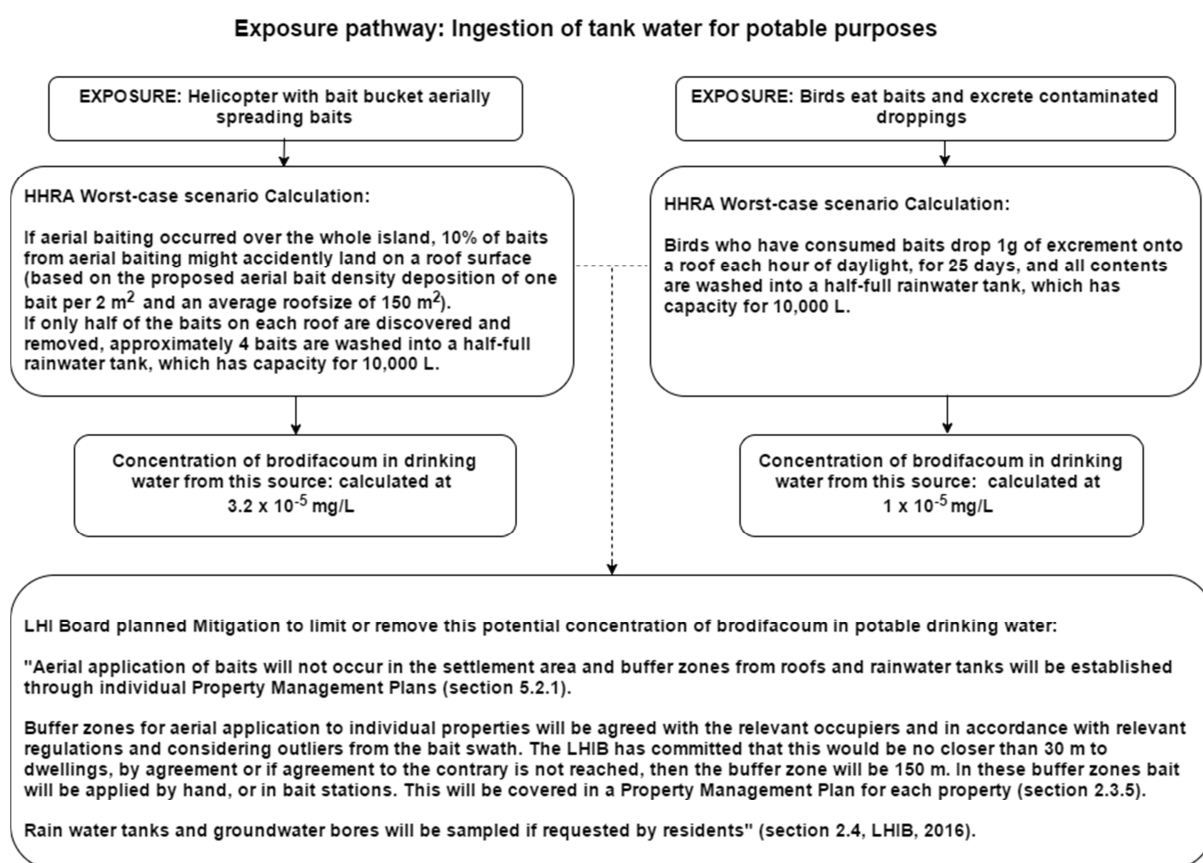


Figure 4: Exposure pathway and calculations for ingestion of tank water for potable purposes in the Ramboll Environ Report, as well as mitigation measures in the LHIB Public Environment Report

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 result 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 eradication programs undertaken internationally to date. More detailed information on rodent eradication programs using the Database of Islands and Invasive Species Eradications (DIISE³, DIISE, 2015) is presented in Appendix 4.

According to the DIISE database, there have been 1,424 successful⁴ 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 successful⁴. 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.

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 aurally. 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 accidentally 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).

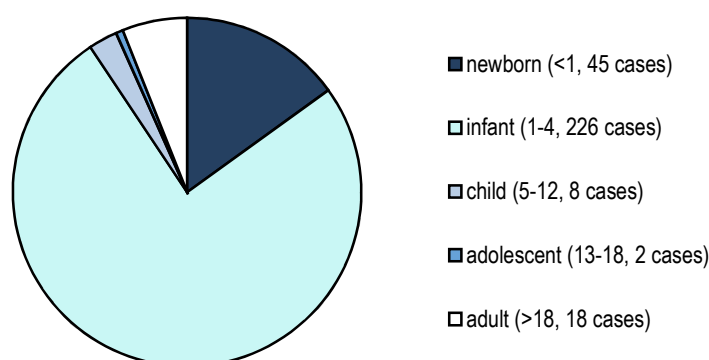


Figure 5: The number of cases from July 2014 to June 2016 involving definite and accidental ingestion of brodifacoum by age category

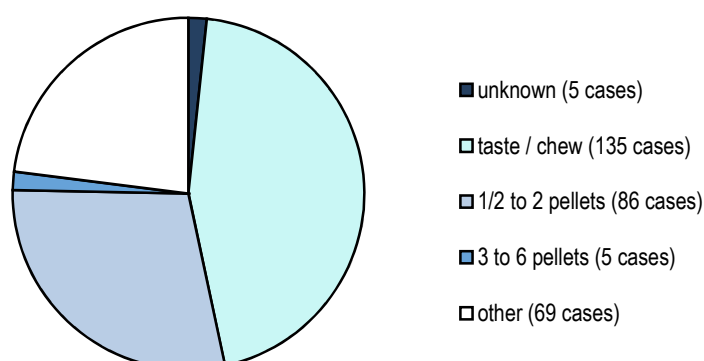


Figure 6: The amount of ingested brodifacoum reported to the NSW PIC from July 2014 to June 2016

Of all patients accidentally 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 accidentally 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 Williamstown 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 gonadotoxins. 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.

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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

HUMAN HEALTH RISK ASSESSMENT PROPOSED LORD HOWE ISLAND RODENT ERADICATION PROGRAM

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Thomas Sendor, Nwakamma Ahubelem**
Checked by **Robert DeMott, Joseph Rodricks**
Approved by **Robert DeMott, Joseph Rodricks**

Ref AS130504

Ramboll Environ
Level 2, Suite 19B
50 Glebe Road
PO Box 435
The Junction
NSW 2291
Australia
T +61 2 4962 5444
F +61 2 4962 5888
www.ramboll-environ.com

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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 km². 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 residents' 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 m²) 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 180° 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 distributors. 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:

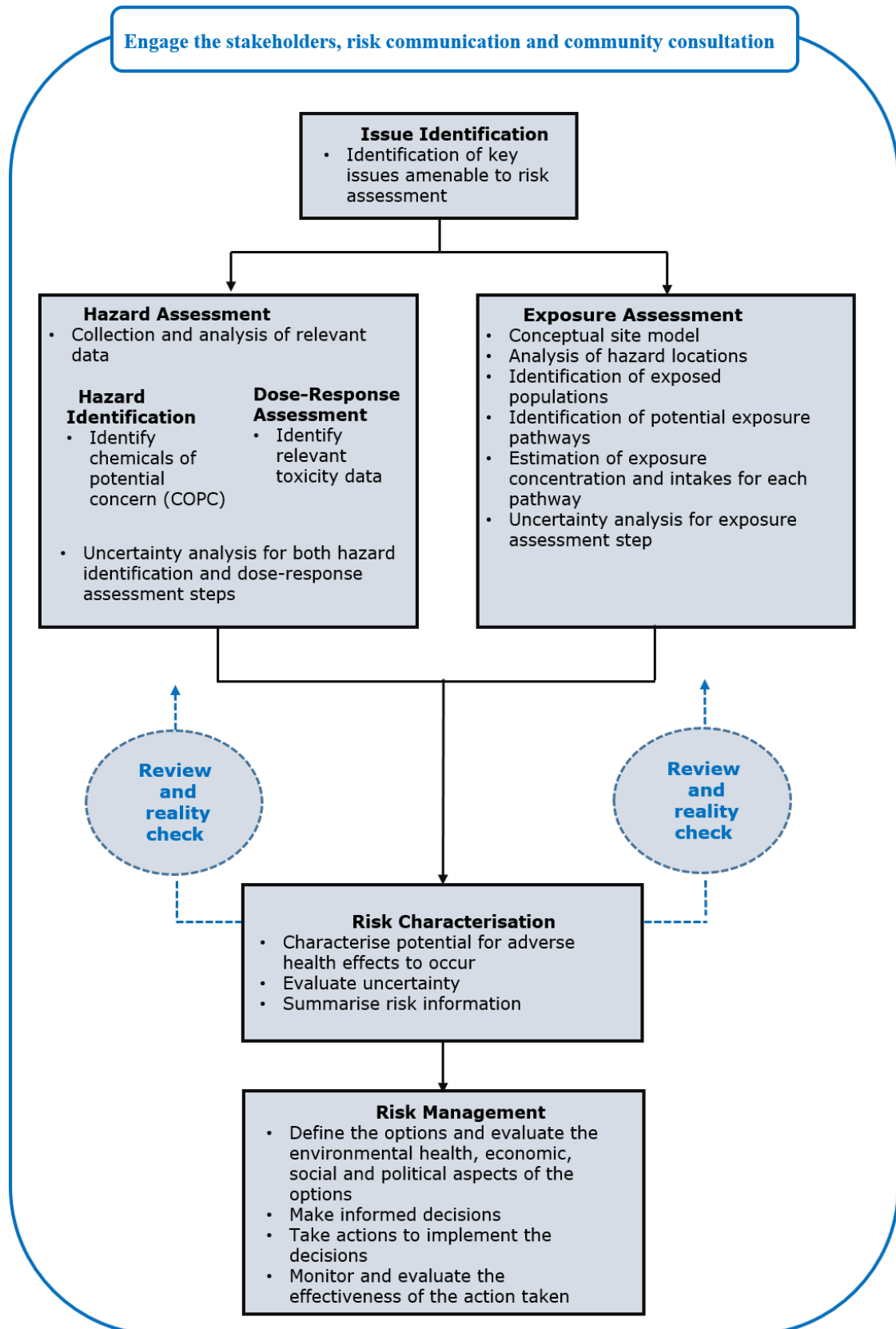
- Section 2: Lord Howe Island Description
- Section 3: Issue Identification
- Section 4: Data Review and Evaluation (including Conceptual Site Model)
- Section 5: Hazard Assessment (Hazard Identification & Dose-Response Assessment)

- 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 km² (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 (Gallirallus sylvestris), once regarded as one of the rarest birds in the world, and the Lord Howe Island Phasmid (Dryococcus 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 km² 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 *Cyathea* 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 *Vespardelus 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 cerambycid 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 tephroleucus*); 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 tuberculata*) 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 Calcareenite with, comparatively minor inclusions of undifferentiated alluvium (gravel and clay) and alluvial clay. The coastal areas comprise Aeolian 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 'calcareenite' 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 (μ S)	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 coumateteryl) 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 coumateteryl and brodifacoum, as has already been seen with a resistance to warfarin by mice on the island. If resistance to coumateteryl 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 OCSE 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, HHRA's 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 food-

grade 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/m² and 3.81 µg/m² the day following the aerial application, with a maximum concentration of 25.2 µg/m².

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/m³), 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 dairy 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·m ³ ·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
Diffusivity in water	Dwater	cm ² /sec	3.35 × 10 ⁻⁶	(Updated Feb 2016) ^b
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 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 it 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/m³). 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 m³/day and a body weight of 70kg for the assessed population, using the following formula:

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

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**). $[3.3 \times 10^{-6} \text{ (mg/kg/day)} \times 0.75 = 2.5 \times 10^{-6} \text{ mg/kg/day}]$

2) RfC derived by multiplying by a body weight of 70 kg, and dividing by a breathing rate of 20 m³/day (enHealth, 2012). $[(3.3 \times 10^{-6} \text{ (mg/kg/day)} \times 70 \text{ kg}) / 20 \text{ m}^3/\text{day} = 1.2 \times 10^{-5} \text{ mg/m}^3]$

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

trays around their homes currently, such isolated indoor uses would not be expected to result in releases to the environment such as would occur with the REP. It is assumed that LHI residents use brodifacoum-containing products such as Talon in accordance with the manufacturer's recommendations such as not removing the pellets from the provided tray, placing the trays in and around buildings (within 2 m) and not placing the trays in the open or locations accessible to children and pets. In addition, areas around homes where residents already have bait trays would be substituted and not duplicated during the placement of bait trays for the REP. Therefore, no TRV adjustment has been made.

6. EXPOSURE ASSESSMENT

Exposure assessment involves the estimation of the magnitude, frequency, extent and duration of exposures to chemicals, and identifies exposed populations and particularly sensitive sub-populations. The exposure assessment process involves:

- identification of exposed populations;
- identification of potential exposure pathways;
- estimation of exposure concentrations for each pathway; and
- estimation of chemical intakes for each pathway for a range of scenarios.

6.1 Exposure Point Concentrations

An exposure point concentration (EPC) is the estimation of the concentration of the source chemical in the medium that the population is exposed to, at the location where exposure is predicted to occur. EPCs are identified for each 'exposure unit', which is defined as the area throughout which a receptor moves and encounters an environmental medium for the duration of exposure. Typically, an individual receptor is assumed to be equally exposed to media within all portions of the exposure unit over the time frame of the risk assessment, which is a protective assumption.

The predicted concentration of brodifacoum in soil, air (dust), sediment, groundwater, surface water, tank water, seafood, and vegetables is described below.

6.1.1 Estimation of Brodifacoum in Surface Soil

As described in **Section 4.4.1.1**, following decomposition of the Pestoff 20R pellet there is the potential for brodifacoum to remain in surface soil. The physical and chemical properties of brodifacoum (**Section 5.1.2**) indicate that brodifacoum is strongly bound to soil particles and studies reported by the World Health Organization (1995b) reported that radiolabelled ¹⁴C-brodifacoum was found to be effectively immobile in a range of soil types tested including coarse sand, sandy clay loam and calcareous sandy loam. Binding to soil was reported to be rapid and strong, and desorption very slow.

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. The half-life of brodifacoum in soil has been reported to be between 12 and 25 weeks (Shirer, 1992; US EPA, 1998; EC, 2010).

Brodifacoum in soil collected from near or under disintegrating baits demonstrated varying concentrations under differing canopy cover conditions:

- Fisher *et al* (2011) reported a brodifacoum concentration of 0.2 µg/g directly under a decomposing pellet or where it had lain for 56 days following an aerial bait drop in grassland areas on Little Barrier Island in New Zealand. This concentration had reduced to 0.03 µg/g after 153 days post aerial bait drop. The reported concentrations were slightly higher in forested areas with a concentration of 0.9 µg/g and 0.07 µg/g of brodifacoum in soil 56 days and 153 days post aerial drop, respectively.
- In a baiting trial conducted in New Zealand in 2002, Craddock (2004) reported soil concentrations of between 0.02 µg/g and 0.2 µg/g from directly beneath disintegrating Pestoff 20R baits (containing 20 mg/kg of brodifacoum) at 56 days after first exposure to the elements. Brodifacoum concentrations were below the laboratory detection limit 84 days after the pellets were placed on the ground.
- In June 2009, soil samples were collected within 20 cm of Pestoff 20R 10 mm baits (containing 20 ppm of brodifacoum) in three habitat types (pasture, bare rock, centim scrub). After 28 days, brodifacoum concentrations in the pasture were 0.0016 µg/g and after 58 days were reported to be 0.002 µg/g (Vestena and Walker, 2010).

The concentration of brodifacoum in soil on LHI following completion of the REP is likely to be localised to the area immediately under or adjacent to a Pestoff 20R pellet. As suggested by the study results described above, brodifacoum in soil will eventually breakdown.

Studies which sampled soil directly beneath or adjacent to decomposed Pestoff 20R pellets reported concentrations of brodifacoum below the laboratory detection limit by between 60 and 180 days following placement in the open (LHIB, 2016).

As a conservative approach in this HHRA, the average soil concentration reported beneath or adjacent to a Pestoff 20R pellet after 38 to 58 days (placed in a variety of habitats ranging from grassland to forested areas) will be used as the soil EPC for this HHRA. This is considered protective because the specified time period corresponds to when the pellets would be expected to be well into their degradation process and the underlying soil would have contained relatively high concentrations of brodifacoum compared to the time immediately after the baiting, when the pellets would not yet have degraded and transferred the brodifacoum into soil, or later times, when the soil concentrations would be decreasing in accordance with the expected half-life. These data are presented in **Table 7**.

Table 7 **Reported Brodifacoum Soil Concentrations either beneath or adjacent to a Pestoff 20R pellet**

Study	Brodifacoum concentration in soil beneath or adjacent to a pellet (mg/kg)	Days post placement of pellet	Habitat pellet placed in
Fisher <i>et al</i> (2011)	0.2	56	Grassland
	0.9	56	Forested
Craddock (2004)	0.02 – 0.2	56	Open areas to full canopy cover
Vestena and Walker (2010)	0.002	58	Pasture
	0.012	38	Bare Rock
	0.045	38	Scrub
Mean concentration (n = 7)	0.20		

The concentration of 0.20 mg/kg represents the mean concentration of brodifacoum beneath or immediately adjacent to a decaying or decayed pellet which has been exposed to the weathering processes for 38 to 58 days post placement. This concentration will be used as the EPC in soil for this HHRA.

The standard soil ingestion rate of 100 mg/day for a child, assumed for HHRA purposes in the enHealth guidance (enHealth, 2012b), was derived from studies that account for the total daily intake of soil constituents by children. This is made up of a combination of actual soil ingested while outdoors and ingestion of dust, which contains both soil transported indoors and other contributions, while indoors. For the HHRA we have accounted for this difference by applying a factor of 50% to account for the fraction of soil from the contaminated location (i.e., the soil immediately beneath the degraded pellet). The remaining 50% of daily intake is assumed to relate to indoor dust and soil from other locations.

The apportionment of soil intake between outdoor soil and indoor dust for risk assessment purposes has been specifically evaluated in recent USEPA guidance documents. In the *Child-Specific Exposure Factors Handbook* (USEPA 2008), EPA effectively recommends that indoor dust be assumed to account for 50% of incidental ingestion:

"When assessing risks for children who are not expected to exhibit soil pica or geophagy behavior, the recommended central tendency soil + dust ingestion estimate is 100 mg/day for children ages 1 to <6 years. If an estimate for soil only is needed, for exposure to soil such as manufactured topsoil or potted plant soil that could occur in either an indoor or outdoor setting, or when the risk assessment is not considering children's ingestion of indoor dust (in an indoor setting) as well, the recommendation is 50 mg/day" (pg. 5-3).

The USEPA *Exposure Factors Handbook* (USEPA, 2011) identifies an intake ratio of 45% outdoor soil and 55% indoor dust (see especially Table 5-1 in USEPA 2011) to account for the cumulative daily intake by a child. The basis for this apportionment is an extensive set of scientific studies that have looked specifically at intake using geochemical and other markers to distinguish outdoor soil from indoor dust. Since this factor has been well studied and incorporated into guidance from international sources, the use of a 50% apportionment factor in the HHRA is consistent with a protective characterisation of soil intake from the locations where pellets have degraded upon the soil. Children are assumed for HHRA purposes to be exposed to soil from such locations, but would also be expected to have exposure to soil from other areas and to indoor dust. While outdoor soil is a component fraction of indoor dust, this would reflect average soil conditions from the area and would not reflect the concentration assumed to be beneath a rodenticide pellet.

6.1.2 Estimation of Brodifacoum in Creek Sediments

Following an accidental release of Pestoff 20R pellets into a tidal marine habitat (approximately 360g of brodifacoum), Primus *et al* (2005) reported a brodifacoum concentration of 0.04 mg/kg was detected in one out of seven sediment samples, one day following the spill. Nine days post spill, brodifacoum sediment concentrations were below the laboratory detection limit.

Operational monitoring of freshwater and marine sediment following an aerial baiting program on Ipipiri Island, sporadically detected a brodifacoum in eight out of 30 samples collected between 0.001 mg/kg and 0.018 mg/kg; with an average concentration of 0.007 mg/kg ($n = 8$) (Vestena and Walker, 2010). These samples were reportedly collected within 20cm of visible baits between 24 hours and two months post aerial baiting.

Sediment concentrations reported by Primus *et al* (2005) following the isolated and concentrated Pestoff 20R spill, is likely to be an overestimate of potential sediment concentrations in freshwater creeks on LHI. Therefore, the average sediment concentration reported by Vestena and Walker (2010) (0.007 mg/kg) following aerial baiting on Ipipiri Island will be used as the sediment EPC in this HHRA. Protectiveness in the use of this EPC relates to the circumstance that the measurements were obtained within 20 cm of visible baits resting on sediment. With the planned density of one 10 mm bait per 1 m² being distributed during the more intensive, first baiting, the measurements from the immediate vicinity of a bait are expected to overestimate the overall sediment concentrations.

6.1.3 Estimation of Brodifacoum in Air (dust)

In 2006, a bait fragmentation field study was undertaken using a 10 mm cereal pellet on a variety of underslung helicopter spreading buckets to estimate the amount of bait breakup occurring due to mechanical abrasion as the bait passes through each bucket during spreading (Torr and Agnew, 2007). The study reported that the amount of fine material produced from each bucket during testing ranged between 0.22% (50 g/bag) and 1.35% (330 g/bag) of the bait placed into the bucket at the start of each test. The study also reported that approximately 130 – 150 g of material less than 2 mm in size was found in a 25 kg bag of Pestoff 20R pellets upon delivery.

Based on the results from the Torr and Agnew (2007) study, it can be assumed that the maximum amount of fine particles to be dispersed during aerial application is the sum of the particles (<2mm size) in the bag (150 g) and particles generated during aerial broadcast (330 g) which equals 480 g. This is approximately 2% of the total bait content.

Assuming the proposed application of 12 kg/ha of pellets will be distributed via aerial spreader buckets in the first drop (at a concentration of 20 mg/kg brodifacoum) and 2% of this weight comprises dust (< 2mm in size), this equates to a total brodifacoum dust concentration of 0.00048 mg/m². Assuming a drop height of 50 m, the concentration of brodifacoum in ambient air during baiting is estimated to be 9.6×10^{-6} mg/m³.

It should be noted that this concentration assumes particle sizes up to 2000 µm in diameter, of which particulates less than 10 µm are considered to be respirable dust. NEPM (2013) assumed that for both indoor and outdoor dust exposures, the respirable fraction is estimated to be 37.5% of the inspirable fraction. This assumes that 75% of the inhaled (respirable) dust will be retained in the respiratory tract (25% exhaled) of which 50% is small enough to reach the pulmonary alveoli, resulting in a respirable fraction of 37.5%.

Therefore, in absence of site-specific information, this HHRA has assumed an ambient air dust EPC of 9.6×10^{-6} mg of brodifacoum/m³ of which 37.5% of this concentration is considered to be respirable (i.e. particles less than 10 µm in diameter).

6.1.4 Estimation of Brodifacoum in Tank Water

Toxikos (2010) estimated the concentration of brodifacoum in tank water should birds consume the bait and excrete droppings onto roof surfaces. Assuming a 1 g bird dropping is deposited onto a roof once per hour (during daylight hours), for 25 days and each dropping has a brodifacoum concentration of 17 µg/g, a water concentration of 0.01 µg/L (or 1×10^{-5} mg/L) was estimated into a half full 10,000 L capacity rain water tank. A number of uncertainties were identified associated with this tank water concentration relating to the ingestion of pellets by birds, the frequency of bird droppings on roof surfaces and the weight of each dropping.

During the aerial distribution of pellets, there is a small potential for the pellets to land on roof surfaces that are used to collect rainwater for potable consumption, including drinking water. This potential is considered to be a 'worst-case' scenario because it does not take into account the buffer zones (30 m or 150 m) around the settlement area, and the fact that aerial distribution of the pellets will not be undertaken in the settlement area (refer to **Section 1.1.2**). Based on the aerial bait density deposition of one bait per 2 m², and a roof surface area of 150 m², a worst-case scenario may result in 10% of pellets accidentally dropped onto a roof surface (i.e. approximately 8 baits). Should baits be deposited on the roof, it is understood that the REP calls for mitigation by team members removing baits on a roof. For the purpose of protectiveness, the EPC is calculated assuming the mitigation team misses 50% of the baits on the roof, in which case, four baits could theoretically be left on a roof surface. This equates to 8 g of bait (each bait weights approximately 2 g), containing a total of 0.16 mg of brodifacoum (each pellet contains 0.02 g of brodifacoum/kg). Assuming all this brodifacoum is washed into a half empty 10,000 L tank (to be consistent with Toxikos's calculations), a rain water concentration of 3.2×10^{-5} mg/L can be derived. This concentration will be used as the theoretical rain water tank EPC in this HHRA.

The EPC used in this HHRA for tank water is the sum of estimated brodifacoum from bird droppings and pellets accidentally deposited onto roof surfaces (i.e., 4.2×10^{-5} mg/L)

6.1.5 Estimation of Brodifacoum in Groundwater

As discussed in **Section 5.1.2**, brodifacoum is essentially immobile in soil hence not expected to contaminate groundwater. At neutral and acidic conditions, the substance adsorbs relatively strongly to soil, resulting in an average soil adsorption coefficient Koc of 9155 L/kg.

Data presented by Broome *et al* (2016) supports the assumption of low brodifacoum concentrations in groundwater where it was reported that based on the analysis of 324 surface water samples, collected over 11 aerial bait applications the detection of soluble brodifacoum is extremely rare. Even after an aerial accidental release of 700 kg of Pestoff 20R pellets over a 30 ha freshwater lake in Fiordland, no residual brodifacoum concentrations were detected in samples of lake water (Fisher *et al*, 2012). The limitations on partitioning to surface water are also applicable to what would be expected to actually occur with regard to groundwater.

To estimate the concentration of brodifacoum in groundwater, Ramboll Environ adopted the approach recommended by ASTM (2010) which estimates the concentration of chemicals in groundwater infiltrating past immobile compounds sorbed to soil. This approach assumes:

- the rate of mass transport within a given phase is slow with respect to the transfer of mass between phases in contact with one another;
- the equilibrium between any two phases is independent of the presence of additional phases; and
- physical contact and mixing among the various phases is 100% efficient, neglecting the effects of heterogeneities and preferential pathways.

Ramboll Environ used the concept of equilibrium partitioning between two phases (e.g. soil to water) to estimate the concentration of brodifacoum in groundwater. Equilibrium partitioning is a common assumption that allows the contaminant concentration in any phase to be expressed as a function of soil concentrations. ASTM (2010) recognises that the assumption of instantaneous equilibrium partitioning will tend to overestimate the contaminant mass transferred from the contaminated soil zone to infiltrating water.

The mathematical equations used to estimate the average brodifacoum concentration in groundwater is presented below, and the equation definitions are presented in **Table 8**.

$$C_L = \frac{C_T}{\left(\frac{\theta_{ws}}{\rho_b}\right) + k_d + H\left(\frac{\theta_{as}}{\rho_b}\right)}$$

$$C_{L \text{ Exposure Unit}} = \frac{C_L}{\left(\frac{A_{soil}}{A_{exposure \text{ unit}}}\right)}$$

$$C_{aquifer} = \frac{C_{L \text{ exposure unit}}}{DAF}$$

Table 8 ASTM (2010) Equilibrium Partitioning Model Equation Parameters

Parameter	Definition
CL	Concentration of brodifacoum in soil leachate (mg/L)
CT	Brodifacoum concentration estimated directly beneath Pestoff 20R pellet (refer to Section 6.1.1) (0.2 mg/kg)
θ_{ws}	Volumetric water content of surface soils (0.12 cm ³ H ₂ O)/cm ³ soil) (sand, silt profile)
ρ_b	Soil bulk density (0.6 g soil/cm ³ soil) (average value from Nanzyo, 2002))
Kd	Soil-water partition coefficient (Koc x foc)
Koc	Organic carbon partition coefficient for brodifacoum (9155 L/kg; Table 5)
foc	Fraction of organic carbon (50 g/kg, low end of range for average values for weathered volcanic material from Nanzyo, 2002)

Parameter	Definition
H'	Henry's Law constant for brodifacoum (unitless) (8.9×10^{-7} ; Table 5)
θ_{as}	Volumetric air content of vadose zone soils ($0.29 \text{ cm}^3 \text{ H}_2\text{O}/\text{cm}^3 \text{ soil}$) (sand, silt profile)
Asoil	Area of impacted soil directly beneath a Pestoff 20R pellet (0.005 m^2 ; assumes a $10 \text{ cm} \times 5 \text{ cm}$ area of impacted soil)
Aexposure unit	Exposure unit area for each pellet (2 m^2 ; assuming one pellet per 2 m^2)
DAF	Aquifer dilution attenuation factor of 20 (US EPA, 2004)
Caquifer	Average concentration of brodifacoum in the aquifer within a 2 m^2 area ($\mu\text{g}/\text{L}$)

The C_T term in the ASTM formula is the concentration of brodifacoum in soil. This value ($0.20 \text{ mg}/\text{kg}$) was assumed based on site-specific derivation for this HHRA (see Section 6.1.1)

The O_{ws} and O_{as} terms are the volumetric water content and air content, respectively, of surface soils. These values (0.12 and 0.29) were taken from the National Groundwater Association (NGWA) table of Default Moisture Soil Parameters and Saturated Hydraulic Conductivity Values Based on USCS Soil Type. For the purposes of this evaluation, the soils were assumed to be classified as 'SM' – Sand, silty based on third party observation of the soils.

The P_b term is the bulk density of the soils. This value was estimated to be $0.6 \text{ grams per cubic centimetre (g}/\text{cm}^3)$. This value was chosen following a literature search for bulk densities of volcanic soils. Figure 4 in a paper by Masami Nanzyo entitled 'Unique Properties of Volcanic Ash Soils' plots the relationship of bulk densities and organic carbon content in volcanic soils. The majority of the samples plotted had a bulk density around $0.6 \text{ g}/\text{cm}^3$.

The K_d term is the soil-water partition (desorption) coefficient. This term was calculated based on the relationship between the organic carbon partition coefficient (K_{oc}) and the fraction of organic carbon (F_{oc}) in the soil.

The reported K_{oc} for brodifacoum is $9,155 \text{ litres per kilogram (L}/\text{kg})$.

The F_{oc} for the site soils was selected from the aforementioned paper by Nanzyo. According to the table, organic content in volcanic soils with a bulk density of $0.6 \text{ g}/\text{cm}^3$ range from approximately $50 \text{ g}/\text{kg}$ to $175 \text{ g}/\text{kg}$. The lower end of the range ($50 \text{ g}/\text{kg}$) was used for HHRA purposes because this assumption is more protective (lower F_{oc} corresponds to more leachability to groundwater).

The H term is the reported Henry's Law Constant for brodifacoum. The value shown on **Table 2**, however, is not the unitless term for H . Conversion to the unitless value (also known as H') was completed using the relationship of H' to H and the inverse of the universal gas constant ($R = 0.08206$) and a temperature ($^{\circ}\text{K} = 298.15$ – conversion of 25°C).

The estimated concentration of brodifacoum in the groundwater (C_{aq}) is calculated from the application of a dilution attenuation factor (DAF) to the C_L (concentration in leachate). A DAF of 20 was selected based on its widespread acceptance as a default value for estimating groundwater concentrations from soil impacts as exhibited in the USEPA Soil Screening Guidance document (USEPA, 1996).

Because the DAF as described and used above assumes that leaching from impacted soil occurs across the entire exposure area, this corresponds to assuming that the soil concentration beneath

a degraded pellet (the assumed soil concentration) applies to the leaching of all soil impacting groundwater. Since the pellets are expected to occur at a density of only approximately 1 per 2 m², the corresponding ratio of the impacted soil area to the area where no pellet was present was used

The ratio of the impacted soil beneath a pellet to the exposure unit of 2 square metres was calculated by assuming the area of the impacted soil beneath a weathered pellet. The area was assumed to be 10 centimetres (cm) by 5 cm. This area (50 square centimetres – cm²) is 1 400th of the entire 2 square metre exposure unit.

An estimated concentration of brodifacoum in groundwater of 5.55×10^{-8} mg/L was derived based on the groundwater modelling methodology described above. While groundwater could theoretically be consumed as drinking water by residents, it is much less likely than tank water to be used for this purpose. And, since the brodifacoum concentration estimated for tank water from bird droppings and pellets falling on the roof (**Section 6.1.4**) is approximately 1000-fold higher than the modelled groundwater concentration (2.2×10^{-5} mg/L vs. 5.5×10^{-8} mg/L), for quantitative risk characterisation purposes the drinking water for the receptors will be assumed to be tank water. The much higher projected EPC for tank water makes this a protective assumption for evaluating drinking water and the results based on this approach will also be protective in the unlikely case where groundwater is used as drinking water.

6.1.6 Estimation of Brodifacoum in Surface Water

LHI has three main streams and a number of ephemeral streams (refer to **Section 2.10**). Assumed groundwater concentrations are likely to be similar to ephemeral streams where the source of water would predominantly be from surface water runoff in contact with soil. Concentrations in the main streams (e.g. Solders Creek) however are likely to be diluted by at least a factor of 10 and therefore have lower brodifacoum concentrations.

Therefore, as a conservative approach in this HHRA the groundwater EPC of 5.55×10^{-8} mg/L will be adopted for surface water. The concept of equilibrium partitioning used to model the groundwater EPC is also relevant for leaching of brodifacoum into surrounding pore water that is subsequently discharged to stream.

6.1.7 Estimation of Brodifacoum in Seafood

The bioconcentration factor (BCF) of a chemical is defined as the ratio between the concentration of that chemical in an organism (or in the fat, or in certain tissue of the organism) and the concentration of the chemical in the aqueous environment. Typical biological factors that affect the BCF include uptake rates and efficiency, body size and percent lipid (especially for non-polar organic compounds).

Bioaccumulation typically increases as water solubility decreases (ANZECC, 2000). An indication of the potential for organic chemicals to bioaccumulate is given by the octanol-water partition coefficient (Kow), which is the ratio of the concentration of a chemical in n-octanol (a surrogate for animal lipid) to the concentration in water, at equilibrium and at a constant temperature (ANZECC, 2000). ANZECC (2000) states that *"chemicals with log Kow values below 3 are not considered to bioaccumulate, while highly fat soluble, lipophilic chemicals are most likely to bioaccumulate. Most of the potentially bioaccumulating compounds have log Kow values between 3 and 7, and bioconcentration tends to decrease beyond 6 due to increasing molecular size and decreasing solubility in fat"*. Based on ANZECC (2000) guidelines, brodifacoum with a log Kow of between 6.2 and 8.5 (**Table 3**) can be expected to have some ability to bioaccumulate in fish tissue.

Experimental data on aquatic bioconcentration of brodifacoum into fish tissue is not available. A bioconcentration factor of 35,134 was calculated by EC (2010) using the equation described below and a log Kow of 6.12 (estimated from measured Koc). ANZECC (2000) states that *"chemicals with BCF values greater than 1000 are assumed to have some potential for bioconcentration..."*.

$$\text{Log } BCF = -0.20 \times \log K_{ow}^2 + 2.74 \times \text{Log } K_{ow} - 4.72$$

Should uptake of brodifacoum occur into fish, studies have shown that brodifacoum tends to accumulate in the liver tissue and not edible portions of the fish. The majority of studies which analysed brodifacoum concentrations in fish tissue one day to 45 days following aerial application of baits, were not detected above the laboratory limit of detection (0.0005 to 0.001 mg/kg) (Empson and Miskelly, 1999, Howald *et al*, 2010; Fisher *et al*, 2011, Maitland, 2012; Masuda *et al*, 2015; Broome *et al*, 2016). Where brodifacoum has been detected in fish, it has been found in liver, gut and whole fish samples with concentrations ranging between 0.002 and 0.315 mg/kg (**Table 9**). When brodifacoum concentrations were initially detected in fish, these concentrations reduced to below laboratory detection limits a further 5 to 32 days following the first aerial application of baits.

Table 9 Summary of Brodifacoum Concentrations Detected in Fish

Source	Location	Program	Tissue Analysed	Maximum Concentration (mg/kg)	Minimum Concentration (mg/kg)	Days post first application
Masuda <i>et al</i> (2015)	Ulva Island, New Zealand	Aerial application of baits	Blue cod (<i>Paraperclis colias</i>) liver	0.092	0.026	45 days
Primus <i>et al</i> (2015)	Kaikoura, New Zealand	Truck spillage of 18 tonnes of Pestoff 20R (20 mg/kg brodifacoum)	Butterfish (<i>Odax pullu</i>) liver	0.04	-	9 days
			Butterfish (<i>Odax pullu</i>) gut	0.02	-	9 days
Pitt <i>et al</i> (2015)	Palmyra Atoll, Equatorial Northern Pacific	Aerial application of brodifacoum baits, 80 kg/ha and 75 kg/ha 10 days apart	Black spot sergeant fish (<i>Abudefduf sordidus</i>) whole fish	0.315 (average = 0.143)	0.05	10 to 15 days
Broome <i>et al</i> (2016)	Wake Atoll, Mid Pacific	Aerial application of brodifacoum baits in 2012	Papio Trevally and Blacktail snapper, whole fish	0.005	0.002	Not reported

Based on the studies discussed above, the average maximum concentration of brodifacoum detected in whole fish tissue samples is 0.16 mg/kg ($n = 2$). Conservatively assuming that 10% of this concentration is present in edible portions of the fish (i.e. not the liver or gut where brodifacoum tends to accumulate), a fish EPC of 0.016 mg/kg can be assumed.

6.1.8 Estimation of Brodifacoum in Vegetables

Brodifacoum is not likely to be transported through soils and taken up into plant tissues since it strongly binds to soil and has a very low solubility.

Only one study was found that sampled plants (grasses) following the application of brodifacoum at 15 kg/ha on Anacapa Island, California (Howald *et al*, 2010). Of the six samples analysed, no detectable concentrations of brodifacoum were detected. Therefore, empirical information regarding brodifacoum concentrations in plants/roots is not available for use in this HHRA.

In absence of chemical-specific information relating to plant uptake or concentration factors for brodifacoum, the 'plant uptake model' recommended by EA (2006, 2009) and used by NEPM (2013) in Australia, will be used in this HHRA. It should be noted however, that use of plant uptake models can be highly variable, and the majority of models tend to over-predict root uptake by at least an order of magnitude (EA, 2006). The adopted 'plant uptake model' predicts a soil-to-plant concentration factor for brodifacoum in fruits and vegetables (green/leafy, tubers and root vegetables), reported in mg/kg fresh weight to mg/kg soil dry weight. This concentration factor is then multiplied by the assumed concentration of brodifacoum in soil (an assumed concentration beneath or immediately adjacent to a degraded/degrading pellet, refer to **Section 6.1.1**) to derive a predicted concentration of brodifacoum in fruit/vegetables. Due to the reported ability of these models to over predict concentrations by 'at least an order of magnitude' (EA, 2006), the estimated fruit and vegetable concentrations were reduced by an order of magnitude. This assumption is supported by the results published by Howald *et al* (2010) which reported no detected brodifacoum concentrations in plant samples.

There is also the potential for soil to adhere to vegetables and subsequently be consumed if the vegetables are not washed properly enough. The potential to consume soil via this pathway is discussed in **Section 4.4.3.1**.

Table 10 presents the input values for the 'plant uptake model' and **Table 11** presents the soil-to-plant concentration factors and concentrations of brodifacoum based on an assumed soil concentration of 0.2 mg/kg (refer to **Section 6.1.1**)

Table 10 Input Values for the 'Plant Uptake Model'

Parameter	Value	Source
Koc (cm ³ /g)	9155	EC, 2010
Log Kow	6.2	ECA, 2013 (refer to Table 5)
Kow	1.58×10 ⁶	ECA, 2013 (refer to Table 5)
Dwater (cm ² /sec)	3.35×10 ⁻⁶	Calculated using US EPA Online Tool (refer to Table 5)
Soil bulk density (g/cm ³)	1.63	Assumed for typical soil in root zone (NEPM, 2013)
Soil-water content by volume (cm ³ /cm ³)	0.13	Assumed for typical soil in root zone (NEPM, 2013)
Fraction organic carbon (foc)	2%	Assumed based on increases of foc following long-term cultivation of home-grown produce (NEPM, 2013)

Table 11 Modelled Soil-to-Plant Concentration Factors and Brodifacoum Concentrations in Fruit and Vegetables

Produce	Soil-to-Plant Concentration Factor (mg/kg)	Modelled Concentration of Brodifacoum in Fruit/Vegetable (mg/kg)
Green/leafy vegetable	0.009	0.002 (0.0002)*
Tuber vegetable	0.403	0.081 (0.0081)*
Root vegetable	0.054	0.011 (0.0011)*
Tree grown fruit	0.002	0.0004 (0.00004)*

Note: *value in brackets represents the fruit and vegetable EPCs that were adjusted by an order of magnitude to account for the ability of plant uptake models to over predict chemical concentrations.

Although it is acknowledged that some residents rely on produce grown on the island at times, due to the reported limitations of the 'plant uptake model' to over predict plant uptake (EA, 2006), and the low likelihood that produce will be grown beneath a Pestoff 20R pellet, it is assumed that 1% of residents fruit/vegetable intake will be from produce grown on the island directly beneath a degrading/degraded pellet with a soil residue concentration of 0.2 mg/kg. This is an approximation based on the expected density of pellets after the REP distribution. As discussed above with regard to groundwater transport, the area of soil over which a pellet degrades and is released is approximately 1/400th of the 2 m² expected to contain each 10 mm pellet. Since plant root networks can spread substantially, this areal proportion was multiplied by 4 (i.e., set to 1%) for the proportion of produce assumed to be grown over impacted soil.

6.1.9 Concentration of Brodifacoum in the Pestoff 20R Pellet

Brodifacoum is present in the Pestoff 20R pellet at a concentration of 20 mg/kg (LHIB, 2016). For the 10 mm-diameter pellets with an approximate mass of 2 g, this corresponds to 0.04 mg of brodifacoum per pellet. For the 5.5 mm-diameter pellets with an approximate mass of 0.6 g, this corresponds to 0.012 mg of brodifacoum per pellet.

6.1.10 Adopted Exposure Point Concentrations

The exposure point concentrations of brodifacoum in the media assessed in this HHRA is presented in **Table 12**.

Table 12 Adopted Brodifacoum Exposure Point Concentrations

Media	Brodifacoum Concentration
Surface soil	0.20 mg/kg
Air (dust)	9.6x10 ⁻⁶ mg of brodifacoum/m ³ of which 37.5% of this concentration is considered to be respirable.
Groundwater	5.5x10 ⁻⁸ mg/L
Surface water	5.5x10 ⁻⁸ mg/L
Tank water	4.2x10 ⁻⁵ mg/L
Sediment	0.007 mg/kg
Seafood	0.016 mg/kg

Media	Brodifacoum Concentration
Vegetables	Refer to Table 11
Pestoff 20R pellet	20 mg/kg

6.2 Human Behavioural and Lifestyle Assumptions

Human behavioural and lifestyle assumptions adopted in the HHRA were obtained from the *enHealth (2012) Exposure Factors* guidance and site-specific information where available.

The human behavioural and lifestyle assumptions adopted in this HHRA for the identified human receptors are presented in **Table 13**.

Table 13 Human Behavioural and Lifestyle Assumptions

Parameter	Toddler (2-3 years)	School Child (8-11 years)	Pregnant Female (19-24 years)	Adult (≥18 years)	Comment
Body weight (kg)	15 ^a	36.5 ^b	66.6 ^c	78 ^d	Body weights recommended by enHealth (2012b), based on Australian Bureau of Statistics survey data from 1995 and 2007/2008.
Exposure duration (years)	1	1	1	1	Assumes brodifacoum will be present in the environment for up to 365 days following completion of first aerial distribution.
DRINKING WATER/SOIL INGESTION RATE EXPOSURE PARAMETERS					
Drinking water Ingestion (L/day)	0.356 ^e	0.48 ^f	2.3 ^g	2 ^h	Ingestion rates are based on estimates of combined direct (drinking water) and indirect water (water used in food preparation) ingestion.
Incidental soil ingestion (mg/day)	100	100	60	60	‘Central tendency’ values from US EPA (2008, 2011) are recommended by enHealth (2012b). Value includes ingestion of outdoor soil plus indoor dust, where 50% of indoor dust is assumed to be derived from outside sources.
Fraction of ingested soil containing brodifacoum	50%	50%	50%	50%	Refer to Section 6.1.1 .
DERMAL CONTACT WITH SOIL EXPOSURE PARAMETERS					
Exposure frequency to surface soil (days/year)	180	180	180	180	Represents the number of days taken for brodifacoum concentrations to reach non-detect concentrations in soil samples collected beneath or adjacent to a Pestoff 20R pellet (refer to Section 6.1.1).
Exposed skin surface area to soil (cm ² /day)	700	1300	2300	2500	Assumes a child or adult touches surface soil with their hands or bare feet. Values represent the mean skin surface area for feet and hands recommended by enHealth (2012b) from Table 3.2.5 (child and pregnant female) and Table 3.2.3 (male adults).

Parameter	Toddler (2-3 years)	School Child (8-11 years)	Pregnant Female (19-24 years)	Adult (≥18 years)	Comment
Soil to skin adherence (mg/cm ² /day)	0.5	0.5	0.5	0.5	Recommended value for children and adults for indoor and outdoor residential exposure scenarios (enHealth, 2012b).
DUST INHALATION EXPOSURE PARAMETERS					
Exposure frequency to airborne dust (days/year)	15	15	15	15	Represents the total number of days, plus an additional five days, during which the pellets will be distributed via aerial and hand broadcasting methods.
Time spent indoors (hours)	22	19	16	16	enHealth (2012b) recommends data derived from Brinkman <i>et al.</i> (1999) for 2-3 year old children. Site-specific assumptions were made for school child, pregnant female and adult based on knowledge of LHI resident's daily activity patterns. Assumes the pregnant female and adult conducts outdoor guided tours of the island.
Time spent outdoors (hours)	2	5	8	8	
Dust lung retention factor (-)	37.5%	37.5%	37.5%	37.5%	Represents the percentage of respirable dust that is small enough to be retained in the lungs (NEPM, 2013). Assumes 75% of inhaled dust will be retained in the respiratory tract of which 50% is small enough to reach the pulmonary alveoli, resulting in a respirable fraction of 37.5%.
LOCALLY CAUGHT/GROWN PRODUCE INGESTION EXPOSURE PARAMETERS					
Exposure frequency for produce ingestion (days/year)	365	365	365	365	Assumes child and adult ingest fruit, vegetables, seafood and dairy grown and/or locally caught on LHI every day of the year.
Percent of vegetable/fruit produce grown on	1%	1%	1%	1%	Assumes 1% of the child and/or adult's daily consumption of produce grown on LHI directly beneath a Pestoff 20R pellet.

Parameter	Toddler (2-3 years)	School Child (8-11 years)	Pregnant Female (19-24 years)	Adult (≥18 years)	Comment
LHI exposed to brodifacoum					
Percent of seafood caught locally from LHI exposed to brodifacoum	1%	1%	1%	1%	Assumes 1% of the child and/or adult's daily consumption of seafood is caught locally from LHI and has consumed a Pestoff 20R pellet before it has the chance to disintegrate in the water column (refer to Section 4.4.3.5).
Vegetable ingestion rate (kg/day)	0.095 ⁱ	0.156 ⁱ	0.224 ⁱ	0.259 ⁱ	Recommended average daily intake of vegetables for a toddler (2-3yrs), school child (9-13 years) and adult (≥ 19 years) (enHealth, 2012; Table 4.4.2).
Fruit ingestion rate (kg/day)	0.178	0.157	0.132	0.216	Recommended average daily intake of vegetables for a toddler (2-3yrs), school child (9-13 years) and adult (≥ 19 years) (enHealth, 2012; Table 4.4.2 and Table 4.4.1). Pregnant female value is for the age group 25-44 years since the 19-24 year data was comparatively lower than all other age groups.
Seafood ingestion rate (kg/day)	0.011	0.015	0.026	0.026	Recommended average daily intake of fish and seafood for a toddler (2-3yrs), school child (9-13 years) and adult (≥ 19 years) (enHealth, 2012; Table 4.4.7)
SURFACE WATER EXPOSURE PARAMETERS					
Exposure frequency to surface water (days/year)	20	20	20	20	Site-specific assumption based on LHI's knowledge of daily activity patterns. Assumes brodifacoum surface concentrations do not reduce overtime, which is a conservative assumption.
Exposure time to surface water (hours/day)	0.5	0.5	0.5	0.5	Site-specific assumption based on LHI's knowledge of daily activity patterns.

Parameter	Toddler (2-3 years)	School Child (8-11 years)	Pregnant Female (19-24 years)	Adult (≥18 years)	Comment
Exposed skin surface area during swimming (cm ² /day)	6100	10,800	18,400	20,600	Mean total skin surface area for each age group recommended by enHealth (2012), data for child and pregnant woman (Table 3.2.4) and male adult (Table 3.2.3)
Incidental surface water ingestion rate during swimming (L/day)	0.025	0.05	0.0125	0.0125	Based on the recommended approximate average water ingestion rate while swimming of 50 mL/hr and 25 mL/hour for children aged ≤15 years, and adults ≥ 15 years, respectively (enHealth, 2012).
SEDIMENT EXPOSURE PARAMETERS					
Sediment ingestion rate (mg/day)	50	50	50	50	Australian sediment ingestion studies not available (enHealth, 2012b). 'Central tendency' values for soil ingestion from US EPA (2008, 2011) are recommended. Value includes ingestion of outdoor soil.
Exposure frequency to sediment (days/yr)	20	20	20	20	Site-specific assumption based on LHI's knowledge of daily activity patterns. Assumes brodifacoum sediment concentrations do not reduce overtime.
Skin surface area exposed to sediment (cm ²)	700	1300	1300	1400	Assumes a child touches sediment with their hands or bare feet, and an adult with their bare feet. Values represent the mean skin surface area for feet and hands recommended by enHealth (2012b) from Table 3.2.5 (child and pregnant female) and Table 3.2.3 (male adults).
Sediment skin adherence (mg/cm ²)	21.5	21.5	0.3	0.3	enHealth (2012) recommended mean soil adherence to skin values for a child playing in sediment exposed via the hands and feet (Table 3.3.5). Adult value represents a 'gardening' exposure scenario (Table 3.3.4).

Notes:

- a) Australian weight data for children below the age of two years not available (enHealth, 2012b). The average mean male (15.5 kg) and female (15.3 kg) weights for a 2-3 year old child (15.4 kg) was rounded to 15 kg, and is the suggested weight for a 2 year old child (enHealth, 2012b).
- b) Average mean weight for male and females aged 8 to 11 years, Table 2.2.1 (enHealth, 2012b).

- c) Mean weight for females aged 19 to 24 years, Table 2.2.1 (enHealth, 2012b).
- d) Average mean weight for male and females ≥ 18 years, Table 2.2.1 (enHealth, 2012b).
- e) Recommended mean water intake for a 2-3 year old child, Table 4.2.5 (enHealth, 2012b).
- f) Recommended mean water intake for a 6 to <11 year old child, Table 4.2.5 (enHealth, 2012b).
- g) Recommended 90th percentile water intake for pregnant and lactating females (enHealth, 2012b).
- h) Recommended lifetime average daily intake for adults (enHealth, 2012b).
- i) HHRA assumes 59% of vegetables are green vegetables, 18% are root vegetables and 23% are tuber vegetables for the adult; and 55% are green vegetables, 17% are root vegetables and 28% are tuber vegetables for the child. This is consistent with NEPM (2013) approaches as recommended by EA (2009).

6.3 Estimation of Chemical Intakes

The chemical intakes are estimated for each receptor and pathway separately for brodifacoum, and the methodology follows that described in enHealth (2012).

The equations used to estimate chemical intake are presented in **Appendix C** for the following exposure pathways:

- Incidental ingestion of soil/sediment
- Incidental ingestion of surface water
- Dermal contact with soil/sediment
- Dermal contact with surface water
- Ingestion of seafood and vegetables
- Outdoor inhalation of dust
- Ingestion of tank water for potable purposes

6.4 Human Exposure Uncertainty

Risk assessment requires the adoption of a series of assumptions relating to human behaviour and characteristics in order to quantify potential human exposure. However the exposure scenarios for the LHI residents and visitors have a degree of uncertainty associated with them. To account for this uncertainty, the assumptions used for the LHI residents and visitors were intentionally chosen to be protective and developed to provide an estimate of reasonable maximum exposures rather than the actual exposures. The specific assumptions and basis for choosing factors expected to be protective that tend to overestimate and ensure against underestimating exposure are discussed for each exposure pathway listed above.

This approach tends to overestimate the associated risks because it is highly unlikely that the level of exposure assumed would occur on LHI and therefore this conservatism, or over prediction, of risk is considered to have more than catered for potential exposure uncertainty in the risk assessment. Uncertainty in the assessment is, therefore, taken into account by erring on the side of over estimation and health protection.

7. RISK CHARACTERISATION

Risk characterisation is the final step in the quantitative risk estimation aspect of the risk assessment process. In this step, information gathered and derived from the toxicity assessment and exposure assessment are combined to derive numerical estimates of potential risk to human health. Conclusions reached during the risk characterisation process conveys the nature and existence of (or lack of) human health risks in a manner useful for decision makers.

7.1 Methodology

In the standard environmental risk assessment method specified by enHealth (2012) and used internationally, potential risks for non-carcinogenic chemicals are represented in the form of Hazard Quotients (“HQs”) computed for each completed pathway of exposure. The HQ is a ratio between the projected daily intake of a chemical by each pathway and the adopted reference values established in the toxicity assessment. Since these values are derived to correspond to doses expected to be safe for the most sensitive endpoints of a chemical and sensitive subpopulations, where the projected daily dose is less than the reference value ($HQ < 1$), the dose is below a threshold recognised to be safe and no adverse effects are expected.

Conversely, if the projected daily dose exceeds the reference value, the HQ will be greater than one and the conclusion that no effects are expected is not supported. In these cases, further evaluation is required to determine the potential for actual health effects, since the reference values correspond to “no-effect” levels.

A determination of the HQ for each pathway is made and these are calculated as follows for the three routes of exposure (oral, dermal, and inhalation):

Oral and Dermal Pathways

$$\text{Hazard Quotient (HQ)} = \frac{\text{Mean Daily Intake (MDI)} \left(\frac{\text{mg}}{\text{kg}} \text{ day} \right)}{\text{Reference Dose (RfD)} \left(\frac{\text{mg}}{\text{kg}} \text{ day} \right)}$$

Inhalation Pathways (dust)

$$\text{Hazard Quotient (HQ)} = \frac{\text{Airborne EPC Concentration} \left(\frac{\mu\text{g}}{\text{m}^3} \right)}{\text{Reference Concentration (RfC)} \left(\frac{\mu\text{g}}{\text{m}^3} \right)}$$

Since an individual might be exposed via several exposure pathways and their overall daily dose corresponds to the sum of exposure by each pathway, the HQs (from multiple exposure pathways) can be summed to calculate an overall risk level, or Hazard Index (HI), as described below:

$$\text{Hazard Index (HI)} = \Sigma \text{Hazard Quotients}$$

Where the HI is less than one, the total daily dose from all relevant pathways is less than the reference values. This outcome supports indicates the overall projected dose is below a threshold recognised to be safe and no adverse effects are expected. And, analogous to the individual pathway HQ, where the HI is greater than one, the projected daily dose exceeds the reference values and the conclusion that no effects are expected is not supported. Again, further evaluation is required to determine the potential for actual health effects. It is particularly

important to consider the reasonable exposure pathways combinations and to assess whether it is likely that the same individual would consistently face the projected exposure by each pathway.

The evaluation of acute health risks for individuals (particularly children) from acute, direct ingestion of rodenticide pellets, identified as being a topic of interest and concern by residents, is not readily characterised using the standard environmental risk metrics (See **Section 5.2.2**). This evaluation is described separately below and, to put the exposures into the most convenient context, risks are characterised using a metric of the number of bait pellets required to correspond to the WHO dosage (WHO, 1995a) recognised to produce observable, readily treated anticoagulant effects. These are the most sensitive effects expected from acute exposures for a child.

7.2 Risk Acceptability Criteria

The HQ and HI approach described above are used under the enHealth guidelines (2012) and by EU and US agencies as the metric to determine the acceptability of non-cancer risks from environmental exposure. The HHRA adopts this approach and the risks relating to the environmental releases from the REP will be concluded to be acceptable if the HI (i.e., projected exposure by all cumulative pathways) is below 1. The HQs are used to determine the risk-driving pathways and, if the HI exceeds 1, these can be the focus of further evaluation or risk management.

With regard to the acute ingestion of bait pellets, using expected actual occurrence of adverse health effects as a metric is not suitable for a risk assessment relating to evaluating and managing a plan such as the REP. Stakeholders including the community, LHIB and OCSE would be expected to require, manage and oversee a prospective pesticide release on the basis of a no-effect standard. Accordingly, no specific amount of acute pellet ingestion will be characterised to be safe. However, interested adults, particularly parents and guardians can refer to the evaluation based on the number of pellets to determine the scale of an incidental ingestion by a child that would be necessary to produce clinically important effects. This type of comparison allows for the margin of safety to be recognised by parents or guardians should a child ingest one or more bait pellets. Refer to **Section 7.6** for a more detailed discussion of the exposure scenario.

7.3 Summary of Quantitative Risk Estimates for Environmental Exposure Pathways

The mean daily intakes (mg of brodifacoum per kg of body weight per day) of brodifacoum and hazard quotients for all human receptors via the exposure pathways assessed quantitatively are presented in **Table 14** and **Table 15**, respectively.

Table 14 Mean Daily Intakes (mg/kg/day) for Brodifacoum Exposure

Exposure Pathway	Toddler	School Child	Pregnant Young Woman	Adult
Incidental soil ingestion	6.67×10^{-7}	2.74×10^{-7}	9.01×10^{-8}	7.69×10^{-8}
Dermal contact with soil	2.33×10^{-7}	1.78×10^{-7}	1.73×10^{-7}	1.60×10^{-7}
Inhalation of outdoor dust during aerial distribution	3.00×10^{-7}	7.50×10^{-7}	1.20×10^{-6}	1.20×10^{-6}
Dermal contact with surface water	1.24×10^{-8}	9.03×10^{-9}	8.43×10^{-9}	8.06×10^{-9}

Exposure Pathway	Toddler	School Child	Pregnant Young Woman	Adult
Incidental ingestion of surface water	9.2×10^{-11}	7.5×10^{-11}	1.0×10^{-11}	8.8×10^{-12}
Dermal contact with sediment	3.51×10^{-7}	2.68×10^{-7}	2.05×10^{-9}	1.88×10^{-9}
Incidental ingestion of sediment	2.33×10^{-8}	9.59×10^{-9}	5.26×10^{-9}	4.49×10^{-9}
Ingestion of fruit and vegetables	1.68×10^{-7}	6.86×10^{-8}	8.73×10^{-8}	8.67×10^{-8}
Ingestion of seafood	1.17×10^{-7}	6.58×10^{-8}	6.25×10^{-8}	5.33×10^{-8}
Ingestion of tank water for potable purposes	9.97×10^{-7}	5.52×10^{-7}	1.45×10^{-6}	1.08×10^{-6}

Table 15 Hazard Quotient Estimates

Exposure Pathway	Toddler	School Child	Pregnant Woman	Adult
Incidental soil ingestion	2.0×10^{-1}	8.3×10^{-2}	2.7×10^{-2}	2.3×10^{-2}
Dermal contact with soil	9.4×10^{-2}	7.2×10^{-2}	7.0×10^{-2}	6.5×10^{-2}
Inhalation of outdoor dust during aerial distribution	2.6×10^{-2}	6.5×10^{-2}	1.0×10^{-1}	1.0×10^{-1}
Dermal contact with surface water	5.0×10^{-3}	3.6×10^{-3}	3.4×10^{-3}	3.3×10^{-3}
Incidental ingestion of surface water	2.8×10^{-5}	2.3×10^{-5}	3.1×10^{-6}	2.7×10^{-6}
Dermal contact with sediment	1.4×10^{-1}	1.1×10^{-1}	8.3×10^{-4}	7.6×10^{-4}
Incidental ingestion of sediment	7.1×10^{-3}	2.9×10^{-3}	1.6×10^{-3}	1.4×10^{-3}
Ingestion of fruit and vegetables	5.1×10^{-2}	2.1×10^{-2}	2.6×10^{-2}	2.6×10^{-2}
Ingestion of seafood	3.6×10^{-2}	2.0×10^{-2}	1.9×10^{-2}	1.6×10^{-2}
Ingestion of tank water for potable purposes	3.0×10^{-1}	1.7×10^{-1}	4.4×10^{-1}	3.3×10^{-1}
Hazard Index (HI = ΣHQ)*	0.86	0.54	0.69	0.57

Notes:

*Acceptable risk level of 1 was adopted (NEPM, 2013)

A review of the hazard index results resented in **Table 15** indicates that the cumulative exposure via all of the specified pathways (i.e. the summation of all exposure pathways) for the toddler,

school child, pregnant woman and adult receptor scenarios is below the reference values representing sensitive, no-effect levels. The HI is less than 1 for each receptor. This outcome supports the conclusion that the projected exposures are below a threshold recognised to be safe and no adverse effects are expected.

The exposure pathways responsible for contributing to more than 70% of the overall HI include (in decreasing order of contribution):

- *Toddler and School Child*: ingestion of tank water for potable drinking use, incidental soil ingestion, and dermal contact with sediment.
- *Pregnant Woman and Adult*: ingestion of tank water for potable drinking use and inhalation of outdoor dust during aerial distribution of pellets.

Even though the Toddler had a lower drinking water ingestion rate and skin surface area compared to the other receptors, the hazard index was highest for the Toddler primarily because this receptor has a lower body weight and therefore they consume more soil and drinking water per unit of body weight, and have a higher ratio of body surface area to volume than older children and adults. For non-carcinogenic effects, smaller child scenarios commonly drive risk estimates due to their low body weight – it takes a less exposure to achieve a given dose in mg/kg body weight. Thus, consideration of the Toddler scenario is protective for older, heavier children that could be exposed via similar pathways and exposure scenarios.

The School Child scenario was included as a second child-based evaluation because the relevant exposure pathways differ, with the school child having higher intensity contact with soil due to outdoor playing activities, larger exposed skin surface area, and other distinct features from the Toddler. The HI was less than 1 for the School Child scenario also, however, demonstrating that when the different pathways relevant for activities by an older child were accounted for the exposures still remained below the threshold level recognised to be safe.

The Pregnant Woman scenario was included specifically to allow for evaluation of circumstances that could relate to reproductive and developmental concerns. Since warfarin is recognised to produce teratogenic effects on the developing musculoskeletal structures for foetuses in some cases where female patients have taken it to control blood clotting conditions, and the EU-derived toxicity reference values specifically account for this endpoint by “reading across” the warfarin effects to apply to brodifacoum, consideration of an adult woman of reproductive age receptor was included. Addressing potential reproductive/developmental effects and evaluating risks to the developing foetus is understandably of interest and concern to the LHI community.

To make the scenario protective and relating to the types of activities common on the island, the Pregnant Woman receptor was also assumed to be out of doors extensively (8 hr/day), as might occur for a resident or visitor hiking in the mountains. This assumption explains why the dust inhalation pathway turned out to be among the highest projected exposure. The Pregnant Woman receptor (as well as the general adult receptor) is assumed to be out of doors throughout the time that dust is settling in her immediate vicinity after the aerial distribution of baits. This is clearly a very protective set of assumed exposures and the HI still remained below 1.

7.4 Evaluation of Potential for Impacts to LHI’s Water Supply

Concerns by the community about drinking water was the basis for including this type of scenario. For the purposes of the HHRA, very unlikely, compounding assumptions were included pertaining to the tank water, but the HQ was less than 1.

The relative contribution of the tank water pathway as among the higher HQs for several receptors is driven by the assumed presence of a number of bait pellets reaching the water tank after deposition from the aerial distribution. Further, the HHRA assumed that only half of the pellets on a roof were found and removed by the REP implementation staff.

The REP specifically provides an exclusion zone and restricts the aerial distribution such that baits are not expected to land on roofs routinely. In addition, the mitigation plans in the REP call for staff to remove any baits accidentally landing on a roof and given the importance of this task, it is unlikely that 50% of these baits would be missed by the mitigation team, as assumed for protective evaluation.

Concern and interest about transfer of brodifacoum from soil to the underlying groundwater was another topic identified by the community. Groundwater concentrations were projected using a model that accounts for partitioning of chemicals between soil and groundwater, and does not include any degradation (See **Section 6.1.5**). Due to the strongly preferential binding of brodifacoum to soil versus water, the projected concentration in groundwater turned out to be low – approximately 1000-fold lower than the projected tank water concentration. Accordingly, it is reasonable and protective to assume that tank water is the important drinking water source for the receptor scenarios. If groundwater was consumed for drinking water purposes without treatment, unlikely given the actual uses described, the exposures would be on the order of 1000-fold less than those from tank water, which as described above yielded risk estimates that were not indicative of a health risk.

7.5 Risk via Consumption of Locally Caught Fish

Another topic of interest and concern to the community was the potential risk from exposure to fish or seafood that had taken up brodifacoum transported to surface water or bait pellets landing in the Lagoon or ocean where brodifacoum could accumulate in the marine foodchain. The potential exposure concentration via this pathway was evaluated using standardized bioaccumulation approaches to address the possible uptake of brodifacoum in fish tissue (See Section 6.1.7).

The HQs calculated based on consumption of fish that had taken up brodifacoum ranged from 0.036 for the Toddler to 0.016 for the adult. Not only are these very low relative to the threshold HQ of 1, the contribution relative to other pathways, such as soil ingestion and tank water ingestion, is very low. This supports conclusions both that transfer of brodifacoum to seafood would not be expected to present a risk to residents or visitors and, further, that this pathway would be a small contributor to human exposures compared to other sources of brodifacoum.

7.6 Characterisation of Risks from Acute Ingestion of Bait Pellets

In addition to characterising potential exposures to brodifacoum released to the environment from the REP, the presence of the bait pellets themselves as possible drawing the attention of children that might play with or ingest them is of interest and concern to the community. While the use of rodenticides is common on the island via the LHIB bait stations and use of bait by individual property holders, the distribution of baits during the REP would be substantially different and bait pellets would be expected to be encountered in the open outdoors. Thus, it is foreseeable that a child could find and ingest bait pellets.

To characterise the extent of ingestion of bait pellets that could produce a recognised adverse effect level for humans, a supplemental approach considering exposure levels recognised to produce anti-coagulant effects was introduced and the adverse effects level (0.015 mg/kg body weight) was determined based on information from US EPA (2013) (**Section 5.2.2**).

The adverse effects level was converted to an ingested dose for the two child receptors using their assumed body weights (15 kg for the toddler, 35.6 kg for the school child) (**Section 5.2.2**). Both sizes of bait pellet contain 20 mg/kg brodifacoum and the 10 mm pellets have an approximate mass of 2 g, while the 5.5 mm pellets have an approximate mass of 0.6 g. These parameter for the bait pellet characteristics can be used to estimate the number of pellets needed to produce the adverse effect level (**Table 16**).

Table 16 **Accidental Ingestion of Bait Pellets – Margin of Safety Information**

Child	Dose to Reach Adverse Effect Level (mg)	Number of 10 mm Pestoff 20R pellets*	Number of 5.5 mm Pestoff 20R pellets**
Toddler	0.23	5.6	13.4
School Child	0.53	18.8	44.5

Notes

*10 mm pellets are approximately 2 g, and at 20 mg/kg brodifacoum, contain 0.04 mg/pellet (20 mg/kg * 0.002 kg)

*5.5 mm pellets are approximately 0.6 g, and at 20 mg/kg brodifacoum, contain 0.012 mg/pellet (20 mg/kg * 0.0006 kg)

To reach the dose corresponding to the human adverse effects level, the toddler would have to ingest more than 5 of the larger bait pellets or more than 13 of the smaller bait pellets. And, the school child would have to ingest approximately 19 of the larger bait pellets or more than 44 of the smaller bait pellets. These values have been calculated on the basis of a one-time, daily dose (i.e., the pellets are consumed all at once, or over the course of a day). In light of the relatively slow elimination of brodifacoum, the scenario could be extended to also apply where a child consumed the same number of total pellets over approximately 2 days. Longer scenarios where children consume bait pellets on multiple consecutive days are not anticipated due to the presence of the dye, which would serve to alert adults to the initial incident. This circumstance provides a margin of safety that parents and guardians can consider with regard to exposure incidents. Given the concentration of 20 mg/kg brodifacoum in the bait pellets that would be used for the REP, it would take substantially more than incidental contact or mouthing and ingesting a pellet or two to reach the threshold from WHO. However, rodenticide bait pellets are not intended for consumption and exposure via this scenario should be minimised to the extent possible.

As determined during the site visit and interview at the island hospital, both the prothrombin time testing used to determine anticoagulant effects and the treatment for such effects (vitamin K therapy) are readily available locally. This provides additional context for parents or guardians with regard to the ability to manage the risks of accidental ingestion. The presence of the green marker dye in the pellets is another factor that is useful in the regard, as accidental ingestion events should be readily recognisable from dye on the face or hands of a child.

For further context to understand the margin of safety between the threshold for adverse effects and the dose of brodifacoum that could be lethal, comparisons can be made to another value. Toxikos (2010) identified 15 mg of brodifacoum as a potentially lethal level for adults. Using the body weights above, this converts to approximately 3.4 mg for a toddler and 8 mg for a school child. For the children, this projected lethal dose is approximately 150 times higher than the threshold for producing readily treatable effects (3.4 mg / 0.023 mg; or 8 mg / 0.053 mg). Estimated lethal levels are not suitable for managing potential risks, but these comparisons provide context to recognise the margin of safety and scale of the ingestion required between minor observable effects and potential lethality.

7.7 Risk to Human Health if the Proposed REP Does Not Proceed

The REP presents specific new potential risks related to rodenticide exposure on LHI by virtue primarily of the proposed distribution of the baits throughout the island and the corresponding releases to a variety of environmental media. However, these are not the only potential risks relating to rodenticides, which are routinely used on the island currently. The LHIB distributes coumatetryl in bait stations and to residents upon request. Commercially available products containing 50 mg/kg brodifacoum are available and used in the settlement area in open bait trays.

To our knowledge, there have been no recorded incidents of rodenticide poisoning producing adverse health effects at the hospital or to poison control authorities. Since observable anticoagulant effects are expected to be the most sensitive effects for such exposures, it is not likely that there are substantial adverse health effects of other kinds occurring in conjunction with the current rodent management program.

However, there is analogy and comparison between the current management program and the REP that is informative to residents and visitors on the island. Under both the current program and REP there is potential for exposure to rodenticides in soil, water and food items (fruit and vegetables, fish). The evaluation in the HHRA documents that the residual levels and likelihood of exposure to these hypothetical sources are low and there are no indications of risks for adverse health effects in relation to the REP. By analogy, the less intense use of rodenticides in the management programme would be expected to result in a similar conclusion for this programme.

In contrast, however, in the absence of the REP, the management program would likely continue indefinitely and the expected trend would be to increase rodenticide use over time, driven by the potential for rats and mice to develop resistance to currently used compounds. Transition to new rodenticides in response to developing resistance would introduce new and unknown risk considerations.

With the REP and if it is successful, there is basis to expect that rodenticide use would be eliminated as it would no longer be necessary. In this case, the pulse of increased use and release of brodifacoum would be followed up by a continuing downward trend of rodenticides in the various environmental media as degradation occurred over time and there was little or no new rodenticide being released.

An additional area of contrast relates to the comprehensiveness and emphasis on management of the REP process. There are extensive plans in place and being optimised and there are financial and staffing resources available and expected to implement the REP in a thorough manner. The current management plan relies on a combination of efforts by the LHIB staff and residents and it is reasonable to anticipate that efforts are not coordinated to the same extent as envisioned in the REP.

7.8 Uncertainty in Risk Characterisation

Uncertainties can be introduced into the risk characterization stage of a HHRA when risk estimates are added across multiple exposure pathways. In some situations, chemicals may not affect similar target organs, may not act via similar mechanisms, or may interact in ways that are not additive. As a result, adding risk estimates may not appropriately reflect the potential risks associated with multiple chemical exposures. Similarly, the risks posed by a chemical following exposure via different pathways may differ in ways that are not adequately reflected by simple addition of the risk estimates derived for each individual pathway.

8. DERIVATION OF ENVIRONMENTAL CRITERIA

During and following completion of the proposed REP, it is understood that LHIB plan to undertake an extensive environmental monitoring program to monitor the breakdown rates of baits, and brodifacoum concentrations in soil (from directly below some baits and control locations), surface water bodies, rainwater tanks and groundwater bores.

To assist with these efforts, Ramboll Environ derived site-specific environmental criteria for soil, sediment, tank water, surface water, groundwater and seafood that take into account the likely exposure scenarios residents and visitors may experience on Lord Howe Island.

The equation below was used to derive the site-specific environmental criteria for brodifacoum in a variety of environmental media.

$$\text{Environmental Criteria} = \frac{\text{Target Hazard Index (1)}}{(\text{Sum of HQ for media}) \times \text{Concentration of Brodifacoum in Media}}$$

The site-specific environmental criteria derived for brodifacoum to assist with post monitoring efforts are presented in **Table 17**. These concentrations are based on the assumed exposure scenarios in this HHRA, and are protective of a 'Toddler' for which the estimated health risks were the highest of the four receptor groups assessed.

Table 17 Site-Specific Environmental Criteria for Brodifacoum

Media	Environmental Criteria
Soil	0.68 mg/kg
Sediment	0.047 mg/kg
Surface water/Groundwater	1.1 x 10 ⁻⁵ mg/L
Seafood (edible flesh)	0.45 mg/kg
Tank water	1.4 x 10 ⁻⁴ mg/L

9. SENSITIVITY ANALYSIS

Sensitivity analysis provides a quantitative estimate of the effect of uncertainty and/or variability in the input parameters on the results of the risk assessment. The analysis should be performed when a risk assessment has been conducted using a deterministic exposure model where a single value has been used to represent likely exposure scenarios (such as ingestion rates). The process involves changing one variable at a time within a defined range while leaving the other variables constant and determining the effect on the output.

The results of the sensitivity analysis are used to identify important input variables (or groups of variables) and develop bounds on the distribution of exposure or risk. A sensitivity analysis can also estimate the range of exposures or risk that result from combinations of minimum and maximum values for some parameters and mid-range values for others (US EPA, 1989). Effort may then be directed to the collection of additional data for these important variables; as additional data is collected, the uncertainty in the 'true' value is reduced (NEPM, 2013).

The sensitivity analysis for this HHRA is provided in **Appendix E**, and was conducted for the 'Toddler' exposure pathways that contributed to greater than 80% of the Hazard Index which included:

- Soil ingestion
- Dermal contact with sediment
- Ingestion of tank water for potable use.

A review of the sensitivity analysis data presented in **Appendix E** identifies that the parameters most sensitive in influencing the resulting risk estimates are associated with:

- Concentration of brodifacoum in tank water
- Concentration of brodifacoum in soil
- Exposed skin surface area for sediment contact.

When the range of identified values for the various assumptions relating to the pathways evaluated in quantitative sensitivity analysis was considered, the corresponding HQs remained less than one with one exception. The tank water concentration, driven by assumptions about the number of bait pellets that could land on a roof and end up reaching the attached water tank, could be projected to vary across a wide range and the corresponding HQ range estimated was from 0.07 to 17 for the toddler receptor. The selected assumptions used in the HHRA yielded an HQ of 0.30 for this receptor and pathway. This outcome indicates that, while expected to be protective (i.e., a substantial number of pellets land on a roof despite the exclusion zone and 50% of these are missed by the removal team), the assumptions about the number of pellets on a roof and the efficiency of removing them are important factors to the outcome of the HHRA and should be managed with high priority.

The concentration of brodifacoum in soil, not surprisingly, is another factor that is subject to wide variability reflecting the differences occurring as pellets degrade over time and the extent that brodifacoum spreads out from the location where the pellet rests. However, even using a broad range of reasonable concentrations, the HQ for the toddler receptor by this pathway still remained below one. For the HHRA, the soil ingested by receptors was assumed to reflect the approximate average concentration detected in sampling of soil directly beneath degraded pellets. Given the expected density of pellets (1 per 2 m² for larger pellets), assuming that a receptor gets the entirety of their exposure from soil immediately beneath a pellet is a highly protective assumption. On this basis, the variability in potential soil concentrations of brodifacoum is expected to be addressed via the assumption that was included in the HHRA and the likelihood for health risks via this pathway is effectively considered.

The exposed skin surface area for sediment exposure is another factor that is subject to substantial variability depending on the nature of the activities undertaken by children playing in a streambed or along the beach on the Foreshore. For the toddler receptor, the value used in the HHRA was the total skin surface area of the hands and feet. If the exposed skin surface area is expanded to include the arms and legs in addition to hands and feet, the HQ remains below one. Accordingly, despite the potential for different assumptions, the outcome of the HHRA would not be altered by a reasonable set of alternative assumptions about exposed skin surface area. The HHRA assumptions are concluded to be protective and the likelihood for health risks via this pathway is effectively considered.

10. CONCLUSIONS

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 proposed for the island. This was undertaken using a standard risk assessment approach recommended by enHealth and also used widely internationally. This approach was supplemented by specific considerations of potential exposures and the nature of potential effects from brodifacoum that have been raised by stakeholders including the island community and the LHIB.

The potential exposure pathways identified by which exposure could occur to brodifacoum relating to the REP were defined and assigned quantitative assumptions that were intentionally expected to be protective (i.e., likely to overestimate exposure). The pathways included for quantitative risk estimation include exposure to soil, air (dust), sediment, surface water, tank water as a drinking water source, seafood, and locally grown fruits and vegetables. Groundwater as a potential drinking water source was also evaluated but since the estimated concentration of brodifacoum was approximately 1000-fold lower in groundwater than tank water, the assessment used the tank water scenario since it was a more protective assumption.

Potential risks via these pathways were then estimated for two exposure scenarios involving children (a toddler and a school child) and two exposure scenarios for adults (an adult woman that might be pregnant and a general adult scenario such as a trekker where the receptors might be out of doors extensively during the time of bait distribution). The risk estimates from each identified exposure pathway were summed for each receptor so that the potential for cumulative exposure via all of the pathways was addressed.

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 (i.e., potential developmental effects linked to anticoagulants in the same chemical family as brodifacoum). This outcome supports a conclusion that adverse health effects would not be expected from the projected brodifacoum exposures related to the REP.

The pathways that contributed most to the projected exposures included ingestion of soil (assumed to be from directly beneath bait pellets), ingestion of tank water as drinking water (assumed to result from bait pellets landing 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. The assumptions relating to these pathways were intended to be protective of the actual extent of exposure likely to occur. In addition, the specifications of the REP recognise that management steps relating to limiting deposition of baits into water bodies and preventing deposition on roofs are relevant and controls for these pathways are expected to be implemented and monitored.

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.

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12. LIMITATIONS

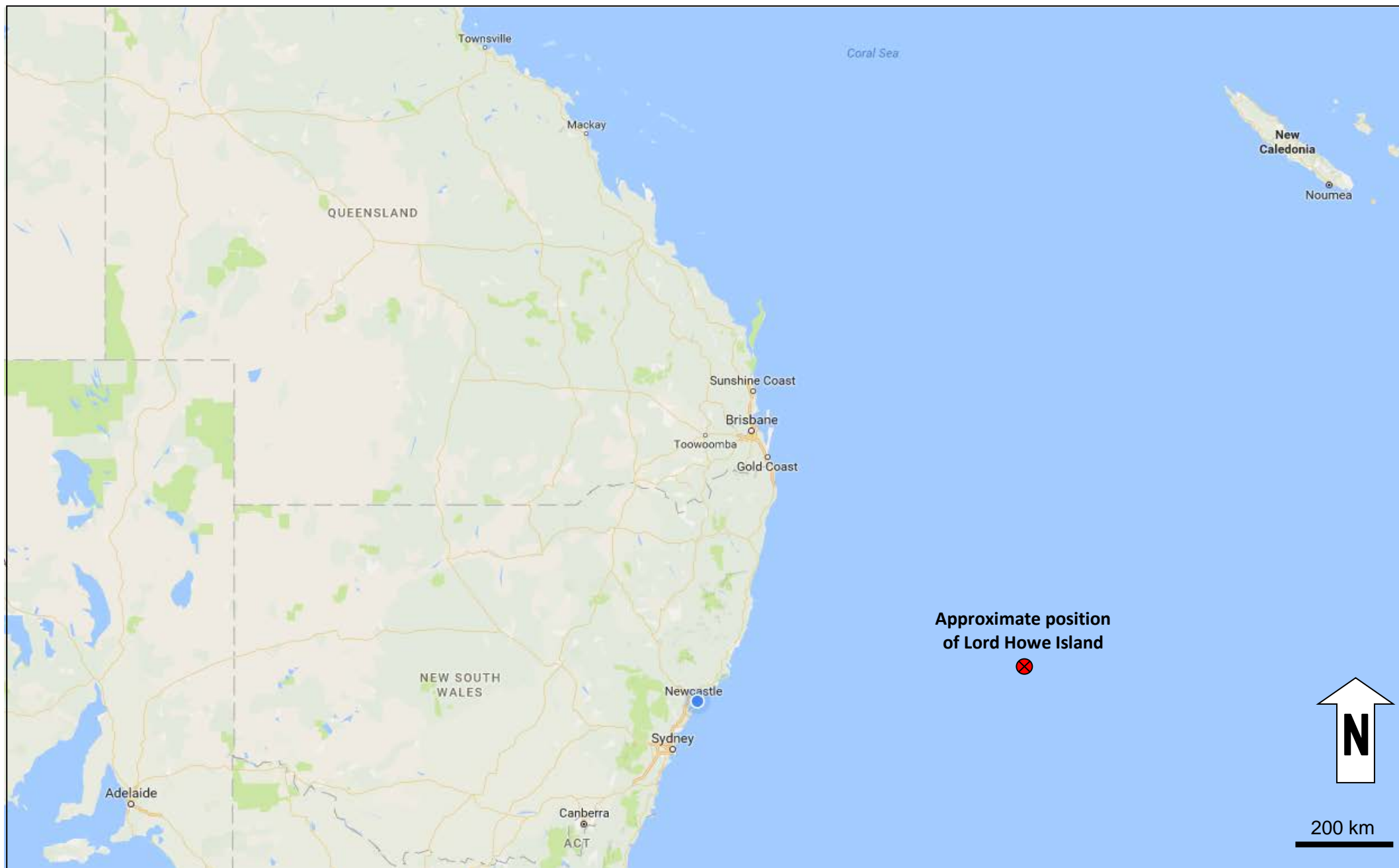
Ramboll Environ prepared this report in accordance with the scope of work as outlined in our proposal to OCSE dated 7 September 2016 and in accordance with our understanding and interpretation of current regulatory standards.

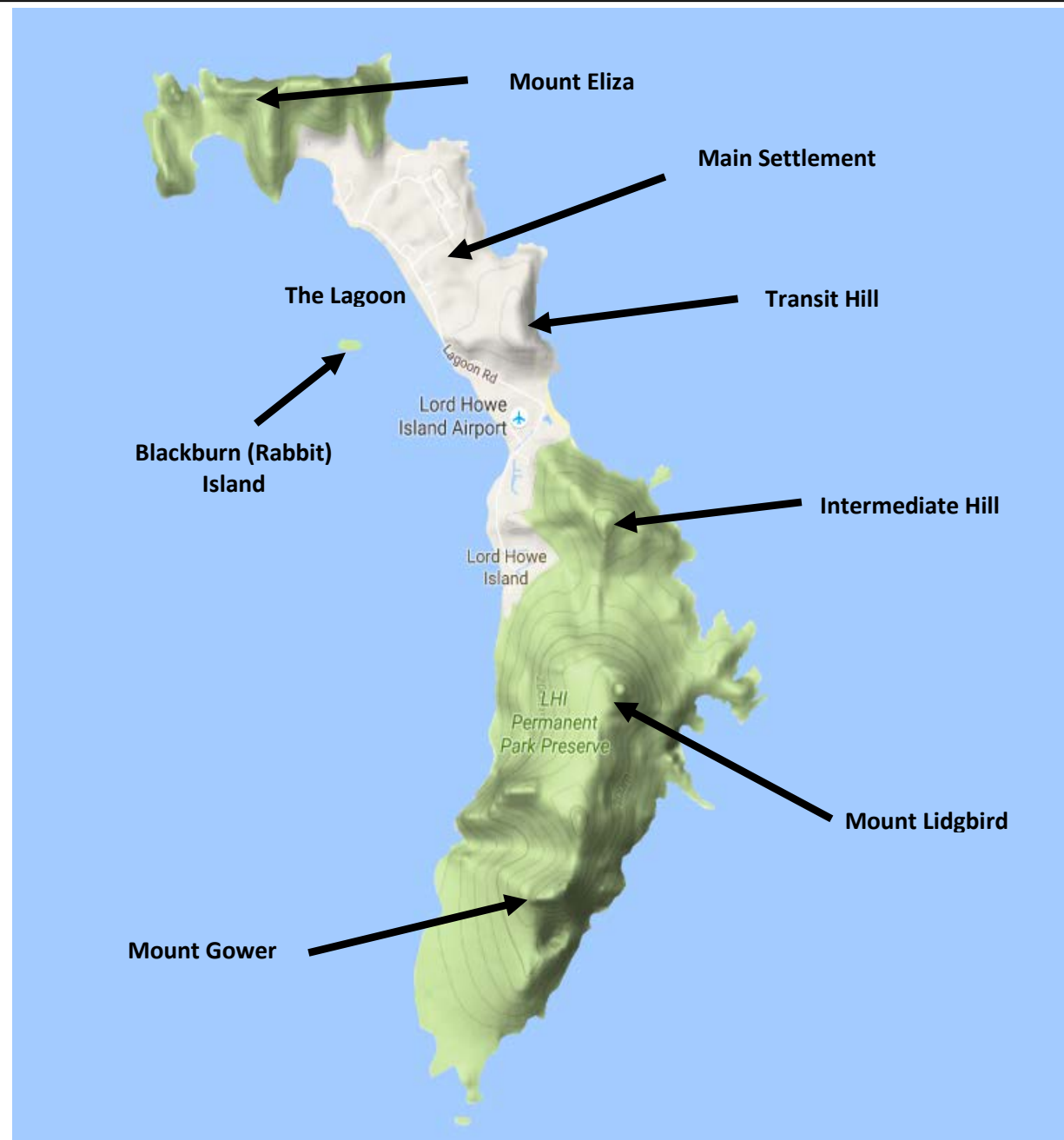
Proposed programs may change over time. This report is based on conditions encountered at Lord Howe Island and the proposed program at the time of the report and Ramboll Environ disclaims responsibility for any changes that may have occurred after this time.

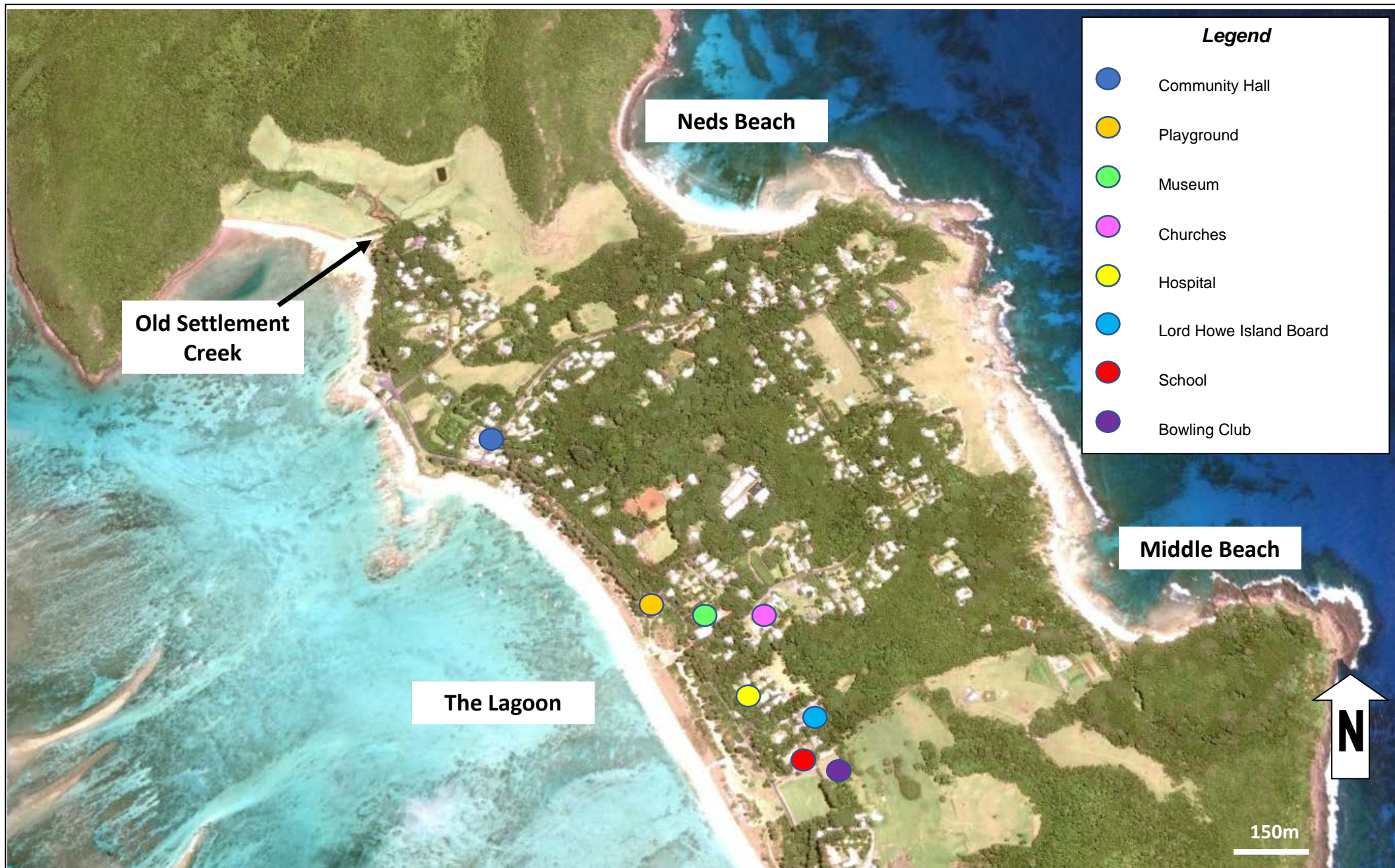
The conclusions presented in this report represent Ramboll Environ's professional judgment based on information made available during the course of this assignment and are true and correct to the best of Ramboll Environ's knowledge as at the date of the assessment.

Ramboll Environ did not independently verify all of the written or oral information provided to Ramboll Environ during the course of this investigation. While Ramboll Environ has no reason to doubt the accuracy of the information provided to it, the report is complete and accurate only to the extent that the information provided to Ramboll Environ was itself complete and accurate. This report does not purport to give legal advice. This advice can only be given by qualified legal advisors

APPENDIX A FIGURES







APPENDIX B

SITE VISIT PHOTOGRAPHS



Photo 1: Rodenticide 'Ratex' currently used by LHIB containing coumatetralyl (0.38g/kg)



Photo 2: Proposed Pestoff (20R) Pellet (used for trial purposes without brodifacoum)


Title:	Lord Howe Island HHRA Site Visit (8-11 November 2016)	Approved: BG	Project-Nr.: AS130504	Date: 15-Nov-16
Site:	Lord Howe Island, NSW			
Client:	NSW Office of the Chief Scientist and Engineer			



Photo 3: Rodenticide 'Talon' currently used by some LHI residents, containing brodifacoum



Photo 4: Example of a bait station proposed to be used during the eradication program


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Site:	Lord Howe Island, NSW	BG	AS130504	15-Nov-16
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Photo 5: Example of a 'L-shaped' rodent bait station currently used by LHIB across the island



Photo 6: Example of a 'T'-shaped rodent bait station currently used by LHIB across the island


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Photo 7: Lord Howe Island Central School



Photo 8: Vegetable garden at the Lord Howe Island Central School


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Client:	NSW Office of the Chief Scientist and Engineer	 ENVIRON		



Photo 9: Lord Howe Island Bowling Club green



Photo 10: Sports ground on Lagoon Road


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Site:	Lord Howe Island, NSW			
Client:	NSW Office of the Chief Scientist and Engineer	 ENVIRON		



Photo 11: View of Lagoon Beach, The Lagoon and Mount Gower in distance looking south



Photo 12: View of Blinky Beach, looking south


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Site:	Lord Howe Island, NSW			
Client:	NSW Office of the Chief Scientist and Engineer	 ENVIRON		



Photo 13: View of Ned's Beach, looking north



Photo 14: View of Kings Beach, looking north


Title:	Lord Howe Island HHRA Site Visit (8-11 November 2016)	Approved: BG	Project-Nr.: AS130504	Date: 15-Nov-16
Site:	Lord Howe Island, NSW			
Client:	NSW Office of the Chief Scientist and Engineer			



Photo 15: Cattle paddocks located south of the airport, looking south



Photo 16: Example of a groundwater extraction bore used as drinking water for cattle


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Site:	Lord Howe Island, NSW			
Client:	NSW Office of the Chief Scientist and Engineer	 ENVIRON		



Photo 17: Example of a groundwater bore with low profile (located adjacent to airport)



Photo 18: View down a concrete lined groundwater bore (located adjacent to airport)


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Site:	Lord Howe Island, NSW			
Client:	NSW Office of the Chief Scientist and Engineer			



Photo 19: Rainwater tank with 'first flush' system



Photo 20: Groundwater filtration unit owned and operated by LHIB


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Site:	Lord Howe Island, NSW			
Client:	NSW Office of the Chief Scientist and Engineer			



Photo 21: Example of a rainwater tank with first flush/sedimentation tank



Photo 22: Example of a rainwater tank collecting water from a roof surface


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Site:	Lord Howe Island, NSW			
Client:	NSW Office of the Chief Scientist and Engineer	 ENVIRON		



Photo 23: Playground on Lagoon Road, looking west towards Lagoon Road



Photo 24: Commercial Nursery owned by 'Kentia Fresh'


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Site:	Lord Howe Island, NSW	BG	AS130504	15-Nov-16
Client:	NSW Office of the Chief Scientist and Engineer			



Photo 25: Waste management facilities, looking north



Photo 26: Community consultation session set up at the Community Hall


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Photo 27: Fish population at Ned's Beach



Photo 28: Foreshore environment at Ned's Beach, looking north east



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Site:	Lord Howe Island, NSW	BG	AS130504	15-Nov-16
Client:	NSW Office of the Chief Scientist and Engineer			



Photo 29: Soldier Creek, looking north



Photo 30 Old Settlement Creek, looking south west

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Site:	Lord Howe Island, NSW			
Client:	NSW Office of the Chief Scientist and Engineer	 ENVIRON		

APPENDIX C

RISK ASSESSMENT ALGORITHMS

Appendix C

Risk Assessment Algorithms

1 Estimation of Chemical Intakes

The algorithms used to estimate chemical intakes for each receptor and chemical of potential concern are presented below, and the definitions for the variables are presented in Table B1.

1.1 Incidental Soil Ingestion (US EPA, 1989)

$$\text{Soil Ingestion Intake} \left(\frac{\text{mg}}{\text{kg}} \text{ day} \right) = \frac{Cs \times IRs \times CF \times FI \times EF \times ED}{BW \times AT}$$

1.2 Incidental Groundwater Ingestion (US EPA, 1989)

$$\text{Groundwater Ingestion Intake} \left(\frac{\text{mg}}{\text{kg}} \text{ day} \right) = \frac{Cw \times IRw \times CF \times EF \times ED}{BW \times AT}$$

1.3 Ingestion of Fruit and Vegetables (US EPA, 1989; EA, 2009)

$$\text{Ingestion of Fruit Intake} \left(\frac{\text{mg}}{\text{kg}} \text{ day} \right) = \frac{Cs \times F_{SD} \times (CF_{fruit} \times IR_{fruit}) \times EF \times ED}{BW \times AT}$$

1.4 Dermal Contact with Soil (US EPA, 2004)

The dermal absorbed dose or dermal intake is estimated using the concept of absorbed dose per event (US EPA, 2004), where the overall absorbed dose depends on the number of events, the adherence factor and the fraction of contaminant absorbed.

$$\text{Soil Dermal Contact Intake} \left(\frac{\text{mg}}{\text{kg}} \text{ day} \right) = \frac{Cs \times CF \times AF \times ABS \times EF \times EV \times ED \times SA}{BW \times AT}$$

1.5 Dermal Contact with Water (US EPA, 1992 & 2004)

The chemical intake via dermal absorption with water is calculated depending on the exposure duration as follows:

$$\text{Water Dermal Contact Intake} \left(\frac{\text{mg}}{\text{kg}} \text{ day} \right) = \frac{DA_{event} \times EF \times EV \times ED \times SA}{BW \times AT}$$

For short duration exposures with organic compounds in water ($t_{event} \leq t^*$):

$$DA_{event} = 2 \times FA \times Kp \times Cw \times \sqrt{\frac{1+3B+3B^2}{(1+B)^2}}$$

For long duration exposures with organic compounds in water:

$$DA_{event} = FA \times Kp \times Cw \times \left[\frac{tevent}{1+B} + 2tevent \left(\frac{1+3B+3B^2}{(1+B)^2} \right) \right]$$

For exposure to inorganic or highly ionised organic chemicals in water:

$$DA_{event} = Kp \times Cw \times tevent$$

1.6 Plant Uptake Models

According to EA (2009) and NEPM Schedule B7 (2013), vegetable and fruit intakes per day are assumed to be the suggested average intakes presented in enHealth (2012). A vegetable intake of 100 g/day and a fruit intake of 180 g/day were estimated for a 2-3-year-old child. The average vegetable and fruit intakes for 19-65 year-old adults were estimated to be 260 g/day and 140 g/day respectively.

For the purpose of assessing exposure via the consumption of fruits and vegetables, produce has been divided into four categories; green vegetables (for example, lettuce and spinach), root vegetables (for example, carrots and onions), tuber vegetables (for example, potatoes) and fruit. The percentage of vegetable consumption comprised of green, root and tuber vegetables was calculated using data provided by EA (2009) and is summarised in **Table C1**.

Table C1 Fruits and Vegetable Categories

Produce group	Adult residents* (%)	Adult residents consumption rate** (g/day)	Child residents* (%)	Child resident consumption rate** (g/day)
Green vegetables	59	153.4	55	55
Root vegetables	18	46.8	17	17
Tuber vegetables	23	59.8	28	28
Tree fruit	100	140	100	180
* Percentage of total vegetables or fruit, from EA (2009e)				
** Calculated based on total vegetable and fruit intakes from Australian data (noted above)				

The concentration of contaminants in edible portions of fruits and vegetables is estimated from the relationship between soil and plant and described using a soil-to-plant concentration factor (CF). For organic compounds, the CF can be estimated using the equations presented by EA (2009) as follows:

Root Crops

CF_{root} (mg/kg fresh weight [fw]plant per mg/kg dry weight [dw]soil)

$$= \frac{\left(\frac{Q}{K_{oc} \times F_{oc}} \right)}{\left[\frac{W}{\rho_p} + \frac{L}{\rho_p} \times 1.22 K_{ow}^{0.77} \right] + (k_g + K_m) \rho_p RV}$$

Tuber Crops

Calculations presented for tuber crops are based on potatoes as representative crops for this group.

$$CF_{tuber} \text{ (mg/kg fw plant per mg/kg dw soil)} = \frac{k_1}{k_2 + k_g}$$

Where:

$$k_1 = k_2 \left(\frac{K_{pw}}{K_{oc} \times F_{oc}} \right)$$

$$K_{pw} = \left(\frac{W}{\rho_p} \right) + (f_{ch} K_{ch}) + \left(\frac{L}{\rho_p} \right) 1.22 K_{ow}^{0.77}$$

$$k_2 = \frac{23 \left(\frac{3600 D_{water} (W^{7/3} / \rho_p)}{K_{pw}} \right)}{R^2}$$

Green Vegetables

CF_{green} (mg/kg fw plant per mg/kg dw soil)

$$= (10^{0.95 \log K_{ow} - 2.05} + 0.82) \times (0.784 \times 10^{-0.434 (\log K_{ow} - 1.78)^2 / 2.44}) \times \left(\frac{\rho_s}{\theta_{ws} + (\rho_s \cdot K_{oc} \cdot F_{oc})} \right)$$

Tree Fruit

CF_{fruit} (mg/kg fw plant per mg/kg dw soil)

$$= \frac{0.001 \times (M_f Q_{fruit} DM_{fruit}) \left(\frac{C_{stem}}{K_{wood}} \right) / M_f}{C_{soil}}$$

Where:

$$C_{stem} (mg/g) = \frac{\left[\left(\frac{C_{soil}}{K_{oc} F_{oc}} \right) 0.756 e^{\frac{-(\log K_{ow} - 2.5)^2}{2.58}} \right] \left[\frac{Q}{M} \right]}{\frac{Q}{K_{wood} M} + k_e + k_g}$$

$$\log K_{wood} = -0.27 + 0.632 \log K_{ow}$$

Table C2 Variables Description for Estimation of Chemical Intakes

Variable	Units	Description
Cs	mg/kg	Concentration in soil
Cw	mg/L	Concentration in groundwater
IRs	mg soil/day	Soil ingestion rate
IRw	L/day	Groundwater ingestion rate

CF	10^{-6} kg/mg	Unit conversion factor
FI	unitless	Fraction ingested from contamination source
EF	days/year	Exposure frequency
ED	years	Exposure duration
BW	kg	Body weight
AT	days	Averaging time ($AT = ED \text{ (yr)} \times EF \text{ (d/yr)}$). US EPA (1989) states that <i>"The averaging time selected depends on the type of toxic effect being assessed...For acute toxicants, intakes are calculated by averaging over the shortest exposure period that could produce an effect, usually an exposure event or day"</i> . For this HHRA, the exposure frequency (and hence averaging time), differed depending on the exposure pathway being assessed (refer to Table 13, Section 6.2 of the main report). This approach is considered to be more conservative than adopting the 'typically larger' averaging time of "365 days/year x ED years) for chronic chemical exposure, and is more appropriate for the type of acute exposure likely to be experienced during the rodent eradication program.
DAevent	mg/cm ² - event	Dermally absorbed dose per event per unit exposed skin area
EV	events/day	Event frequency
SA	cm ²	Skin surface area available for contact
Cw	mg/L	Concentration in water
AF	mg/cm ² - event	Adherence factor of soil to skin
ABS	unitless	Dermal absorption fraction (chemical-specific)
FA	unitless	Fraction absorbed from water
Kp	cm/hour	Dermal permeability coefficient of compound in water (chemical-specific)
τ_{event}	hours/event	Lag time per event (chemical-specific, refer to Appendix B of US EPA (2004))
t^*	hours	Time to reach steady state = $2.4 \tau_{\text{event}}$
t_{event}	hours/event	Event duration
B	unitless	Ration of the permeability coefficient of a compound through the stratum corneum relative to its permeability coefficient across viable epidermis (refer to Equation A.1 in Appendix A of US EPA (2004)).
$Q_{\text{root crops}}$	cm ³ /day	transpiration stream flow rate, (assumed equal to the default of 1000)

K_{oc}	cm^3/g	organic carbon-water partition coefficient for the contaminant, (compound-specific)
F_{oc}	unitless	fraction of organic carbon in the soil
K_{ow}	unitless	octanol-water partition coefficient, (compound-specific)
W	g/g	root water content, (assumed equal to the default of 0.89)
L	g/g	root lipid content on a mass basis, (assumed equal to the default of 0.025)
ρ_p	g/cm^3	plant root density, (assumed equal to the default of 1)
$k_{g(\text{root crops})}$	unitless	first order growth rate constant, per day (assumed equal to the default of 0.1)
K_m	unitless	first order metabolism rate constant, (per day) (assumed equal to the default of 0)
RV	cm^3	root volume, (assumed equal to the default of 1000)
k_1	unitless	rate of chemical flux into the potato, (per hour)
k_2	unitless	rate of chemical flux out of the potato, (per hour)
$k_{g(\text{tuber crops})}$	unitless	first order growth rate constant, per day (assumed equal to the default of 0.0014)
F_{oc}	unitless	fraction of organic carbon in the soil,
K_{oc}	cm^3/g	organic carbon-water partition coefficient for the contaminant, (compound-specific)
D_{water}	m^2/s	chemical diffusion coefficient in water, (compound-specific)
ρ_p	g/cm^3	potato tissue density, (assumed equal to the default of 1)
R	m	radius of the potato, (assumed equal to the default of 0.04)
W	g/g	water content of potato, (assumed equal to the default of 0.79)
K_{pw}	cm^3/g	equilibrium partition coefficient between potato and water
f_{ch}	unitless	fraction of carbohydrates in the potato, (assumed equal to the default of 0.209)
L	g/g	lipid content of potato on a mass basis, (assumed equal to the default of 0.001)

K_{ch}	cm^3/g	carbohydrate-water partition coefficient (calculated from chemical lipophilicity according to Table B3)
ρ_s	g/cm^3	dry soil bulk density
θ_{ws}	cm^3/cm^3	soil-water content by volume
M_f	g fw	mass of fruit (assumed equal to the default of 1)
Q_{fruit}	$\text{cm}^3/\text{g fw}$	water flow rate per unit mass of fruit, (assumed equal to the default of 20)
DM_{fruit}	g/g	dry matter content of fruit (assumed equal to the default of 0.16)
C_{stem}	mg/g	chemical concentration in the woody stem
K_{wood}	mg/g dw wood per mg/cm^3 water	wood-water partition coefficient,
C_{soil}	mg/kg dw	total chemical concentration in soil, (assumed to be 1 for establishing ratio)
$Q_{\text{(tree fruit)}}$	cm^3/year	transpiration stream flow rate, (assumed equal to the default of 25,000,000)
M	g dw	mass of the woody stem, (assumed equal to the default of 50,000)
k_e		rate of chemical metabolism, (per year) (assumed equal to the default of 0)
$k_g_{\text{(tree fruit)}}$	unitless	rate of dilution due to wood growth, (per year) (assumed equal to the default of 0.01)

Table C3 Chemical Lipophilicity Table for Deriving K_{ch}

Chemical log K_{ow}	Chemical K_{ch} (cm^3/g)
<0	0.1
≥ 0 but <1	0.2
≥ 1 but <2	0.5
≥ 2 but <3	1
≥ 3 but <4	2
≥ 4	3

2 References

EA (2009) Updated technical background to the CLEA model. Science report SC050021/SR3, Environment Agency, Bristol, UK.

enHealth (2012) Australian Exposure Factor Guide. Commonwealth of Australia.

NEPM (2013) Schedule B7 Appendix B, Equations for Derivation of HILs and Interim HILs

US EPA (1989) Risk assessment guidance for Superfund, Vol I. Human health evaluation manual (Part A) Interim final report, EPA/540/1-89/002, United States Environmental Protection Agency, Washington, DC, USA.

US EPA (1992) Dermal Exposure Assessment: Principles and Applications. EPA/600/8-91/011B. Office of Research and Development.

US EPA (1989) Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part A). United States Environmental Protection Agency, Washington, DC, USA.

US EPA (2004) Risk Assessment Guidance for Superfund, Vol I, Human health Evaluation Manual (Part E), Supplemental guidance for dermal risk assessment. United States Environmental Protection Agency, Washington, DC, USA.

APPENDIX D

ISSUES RAISED BY THE LHI COMMUNITY

Table D1 Summary of Human Health Related Issues and Concerns Raised by the Lord Howe Island Community

Human Health Issue/Concern	Section of HHRA Report Where Issue/Concern is discussed
Potential health risks from dust exposure during distribution of pellets from helicopter and hand broadcasting methods	4.4.3.2, 6.1.3, 6.3, 7.3
Potential for brodifacoum to enter the groundwater table and drinking water supplies	4.4.3.7, 5.1.2, 6.1.4, 6.1.5, 6.3, 7.4
Potential for brodifacoum to bioaccumulate in fish and health risks to residents/visitors who consume locally caught fish	4.4.3.5, 5.1.3, 6.1.7, 6.3, 7.5
Potential risk to school children due to the 'bare foot' policy	4.4.2, 4.4.3.1, 5.1.6.2, 6.1.1, 6.3
Potential for brodifacoum to cause birth defects and risks to pregnant and breastfeeding women (and their foetuses)	4.4.2, 5.1.4, 5.1.5, 5.1.6.1, 7.3
Solubility of brodifacoum and its potential to enter water ways	2.1.2, 4.4.3.6, 4.4.3.7, 5.1, 6.1.5, 6.1.6, 6.3, 7.4
Exposure to brodifacoum via flooding on the island	2.10, 4.4.3.6, 4.4.3.7, 6.1.5, 6.1.6
Ecological impacts of the eradication program to terrestrial and marine receptors	2.7, 2.8, 3.3
Mental health issues (e.g., stress, anxiety) experienced by the community due to the proposed eradication program	3.3
Potential for children to pick up and ingest the Pestoff (20R) pellets and associated health risks	4.4.3.9, 5.2.2, 7.6
Potential for brodifacoum to be 'washed off' down hillsides and into residential properties	4.4.3.7, 4.4.3.8, 5.1.2
The length of time for the Pestoff (20R) pellets to breakdown in the environment, persistence of brodifacoum in the environment	5.1.3.1, 6.1.1
Actions to be taken if community members 'feel sick'	2.6, 5.1.5
Signs and symptoms of poisoning by brodifacoum exposure	5.1
Risks to community members who are taking coumarin based derivatives such as warfarin for medical purposes	2.6, 4.4.2, 5.1.6.3
Questions regarding the concentration of brodifacoum in the environment on Lord Howe Island currently (i.e. before the proposed eradication program)?	5.2.3
Perception that the method for distributing the Pestoff (20R) pellets is not controlled, and the pellets will be deposited in areas they are not meant to go (e.g. on roofs)	1.1.2, 4.4.3.6, 6.1.4
Potential for the Pestoff (20R) pellets to be deposited in bore water wells that are not covered, and the associated health risks	4.4.3.6, 6.1.4, 7.4
Concerns regarding entry of pellets and dust from pellets entering into rainwater tanks via roofs and gutters	4.4.3.6, 6.1.4, 7.4
Potential impacts to water originating from Mount Gower	1.1.2, 4.4.3.7
Potential toxic effects from the antidote (Vitamin K)	Beyond the scope of HHRA
Potential for hikers to track soil from the mountain into the community area	6.1.1
Health risks from use of Talon and Ratex currently used by community	1.1.1, 7.7

Why can't bait stations be used across the island rather than distribution of pellets? Community would feel 'safer' if only bait stations were used.	1.1.1, 1.1.2
Concerns that the total concentration of brodifacoum to be distributed will exceed maximum permissible levels	6.1, 7.3
Concerns that brodifacoum is a teratogen	5.1
Concerns that brodifacoum is extremely bioaccumulative in the environment	5.1.3, 4.4.3.5, 5.1.3, 6.1.7, 6.1.8
Concerns regarding the toxic effects of brodifacoum during early childhood exposure	4.4.2, 5.1.6.2, 7.3
Concerns regarding the toxicity reference value adopted in the HHRA.	5.2
Concerns regarding tank water contamination from poisoned rats and birds.	6.1.4

APPENDIX E

SENSITIVITY ANALYSIS

Variable (Toddler)	Range			Toddler Hazard Quotient			Sensitivity Level/Comment
	HHRA Value	Minimum Value	Maximum value	HHRA Value	Minimum Value	Maximum value	
Incidental Ingestion of Soil							
Soil ingestion (mg/day)	50	25	100	0.2	0.1	0.4	The amount of soil ingested is directly proportional the resulting hazard quotient. The adopted soil ingestion value is likely to be an overestimate of actual soil ingested that is located directly below a Pestoff 20R pellet as the likelihood that a child will ingest soil below a pellet is low. The maximum ingestion value assumes that all of the soil ingested per day is directly from soil beneath a Pestoff 20R pellet which is an unlikely scenario.
Soil concentration (mg/kg)	0.2	0.002 ^a	0.9 ^b	0.2	0.002	0.9	The average soil brodifacoum concentration adopted as the EPC in this HHRA is considered to be a conservative assumption given the number of studies that reported non-detect soil concentrations, and the reported degradation rate of brodifacoum in soil (Section 6.1.1).
Dermal Contact with Sediment							
Skin exposed (cm²)	700	300 ^c	2800 ^d	0.14	0.06	0.57	The HHRA assumed a child may play in sediment along a creek edge with hands and feet exposed. Even if the arms and legs are also exposed, the resulting hazard quotient is still within acceptable levels (i.e. less than 1).
Sediment adherence factor (mg/cm²)	21.5	0.5 ^e	22.4 ^f	0.14	0.003	0.15	The majority of sediment adheres to a person's foot when walking on sediment, and the majority of this value relates to foot exposure. It is more likely that a child on LHI will have contact with sediment via bare feet, than with just hands. Hence the value adopted in this HHRA is considered to be reasonable (i.e. hands and feet).
Sediment concentration (mg/kg)	0.007	0.001 ^g	0.018 ^g	0.14	0.02	0.36	The likelihood that a child is exposed to 0.007 mg/kg of brodifacoum on their hands and feet is low given that brodifacoum is known to adhere strongly to organic particles and settle out. Hence the wide distribution

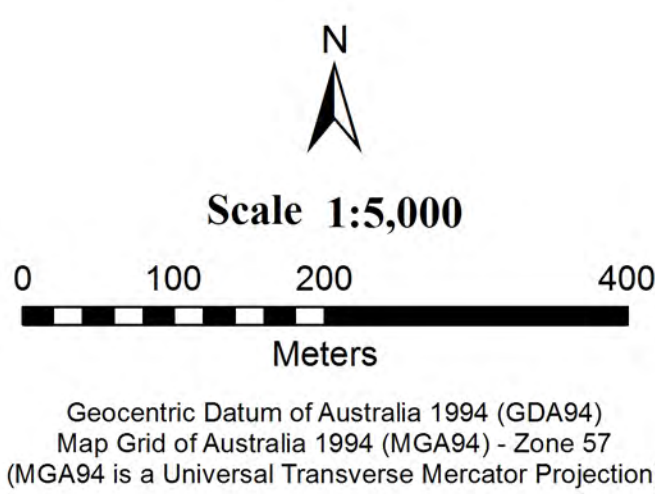
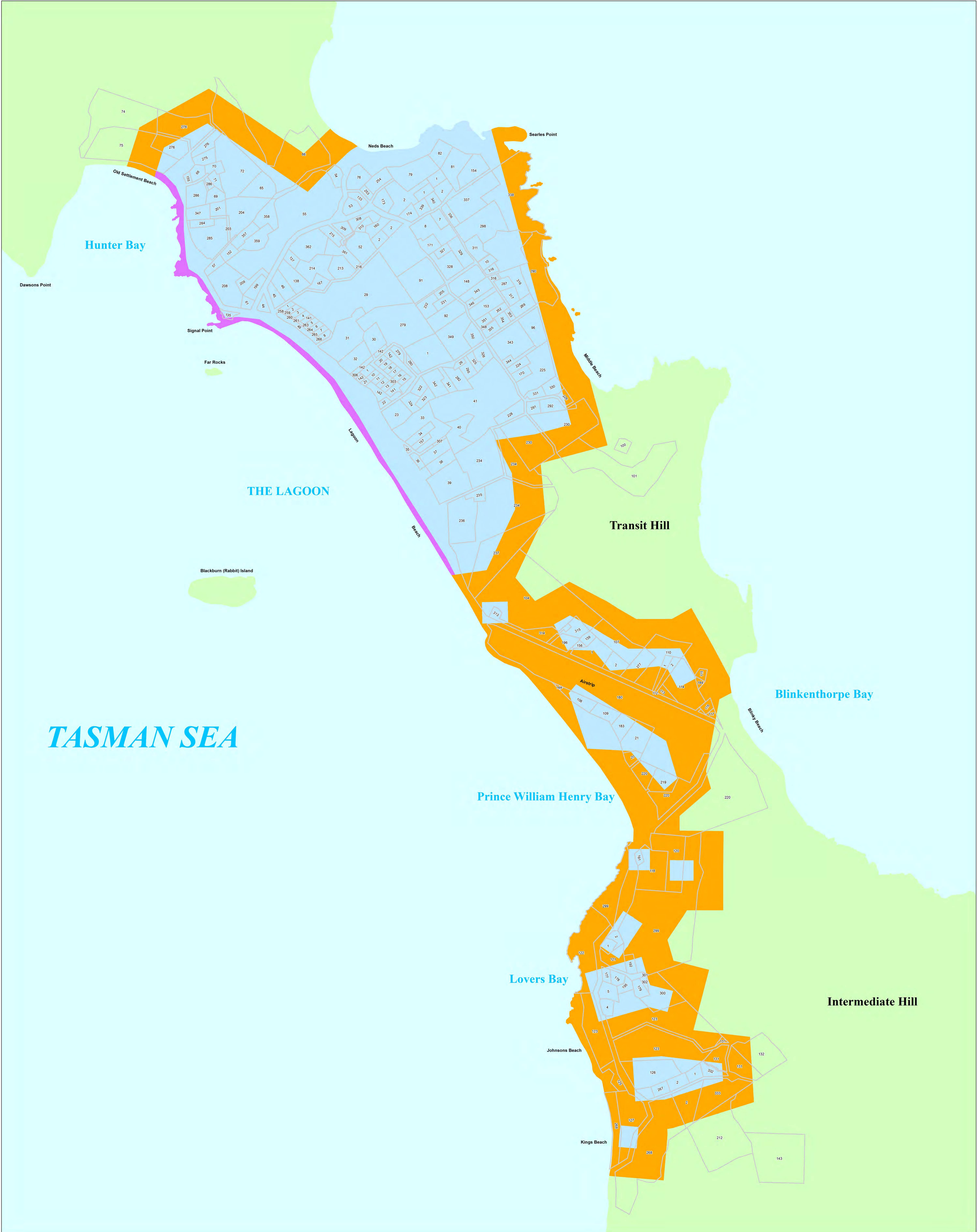
							of concentrated amounts of impacted sediment is low. Even if the maximum reported sediment concentration is adopted, the resulting hazard quotient is still within acceptable levels (i.e. less than 1).
Ingestion of Tank Water for Potable Use							
Water ingestion (L/day)	0.356	-	0.7 ^h	0.30	-	0.31	When the 90 th percentile water ingestion rate is used for the child, the hazard quotient increases by almost two orders of magnitude however the health risks are within acceptable levels (i.e. less than 1).
Tank water concentration (mg/L)	4.2x10 ⁻⁵	1.0x10 ⁻⁵ⁱ	2.4x10 ^{-3j}	0.30	0.07	17	LHIB (2016) identifies a number of procedures that will take place during aerial baiting to reduce the likelihood that bait will land on roof surfaces and enter rainwater drinking supplies. This HHRA has assumed these procedures will take place, with a small amount of contingency in the event that some pellets enter rainwater tanks. Should the procedures fail, and pellets land on the roof surfaces at a density of one bait per 2 m ² and enter drinking water supplies, unacceptable health risks are likely to result.

Notes:

- Minimum brodifacoum soil concentration reported by Vestena and Walker (2010) (Table 7 of Section 6.1.1)
- Maximum brodifacoum soil concentration reported by Fisher *et al* (2011) (Table 7 of Section 6.1.1).
- Mean surface area for hands only for a 2-3 year old child (enHealth, 2012; Table 3.2.5)
- Mean surface area for hands, arms, feet and legs for a 2-3 year old child (enHealth, 2012; Table 3.2.5)
- Sediment adherence factor for a child playing in sediment with contact via hands only (enHealth, 2012; Table 3.3.5)
- Sediment adherence factor for a child playing in sediment with contact via hands, arms, feet and legs (enHealth, 2012; Table 3.3.5)
- Maximum and minimum brodifacoum sediment concentrations reported by Vestena and Walker (2010) (Section 6.1.2).
- 90th percentile value for a child aged 2-3 years (enHealth, 2012; Table 4.2.5)
- Assumes brodifacoum enters rain water tanks via bird droppings, and no pellets are deposited onto roof surfaces during aerial deposition (Section 6.1.4)
- Assumes brodifacoum enters rain water tanks via bird droppings, and pellets are deposited onto a 150 m² roof surface at the anticipated aerial distribution rate of 1 pellet/2 m² (Section 6.1.4).

APPENDIX F

RODENT ERADICATION PROGRAM FIGURE



- Portion Boundary
- Aerial Broadcasting
- Hand Broadcasting
- Hand Broadcasting/Bait Station
- Combination of Aerial/Hand Broadcasting/Bait Station depending on PMP outcomes

Lord Howe Island
Rodent Eradication Program



DISCLAIMER
This map is not guaranteed to be free from error or omission. Therefore, the Lord Howe Island Board and its employees disclaim liability of any act done or omission made on the information on the map and any consequences of such acts or omissions.

APPENDIX 3 SUMMARY OF SUBMISSIONS TO THE HHRA

LHI community members and other stakeholder were invited to provide submissions to the OCSE on the HHRA to ensure all human health matters of concern by the community were considered in the HHRA report. Four submissions were received. The information from these submissions have been summarised below. No attempts have been made to verify the information included in the submissions.

HHRA Comments

- The REP presents a serious risk to human health – short, medium and long term health effects need to be explored
- The HHRA needs to consider the 2014 opinion of the European Chemicals Agency on brodifacoum
- The REP needs to address the concerns raised by SA Health in their review of the previous HHRA
- The HHRA needs to consider
 - The toxicity to aquatic organisms and subsequent bioaccumulation and risk to human health from eating seafood
 - The survival of brodifacoum in organisms, sediments and soil and its subsequent accumulation up the food chain
 - Pellets and dust from pellets entering the waterways and ground water and its subsequent use for livestock and produce
 - Pellets and dust from pellets entering into rainwater tanks via roofs and gutters
 - All locally produced food– milk, meat, eggs, vegetables and fruit
 - Ingestion of pellets by children
 - Exposure to other vulnerable groups including children, the elderly, pregnant women and those taking medications likely to interact with brodifacoum
 - Exposure to the dust from the pellets

Other comments raised by stakeholders

The LHIB was provided with this summary of the issues raised in the submissions, and responded with the relevant section of their reports: Lord Howe Island Rodent Eradication Project NSW Species Impact Statement (LHIB SIS; 2017), and Lord Howe Island Rodent Eradication Project Public Environment Report (LHIB PER, 2016). No attempt by the OCSE has been made to judge the adequacy of these measures.

Non-HHRA Issue/ Concern	Report and section where issue/concern is discussed
A similar REP has not been undertaken on inhabited island with similar populations to LHI and unlike other area, most people cannot relocate during the REP	Eradication programs on inhabited islands discussed in LHIB SIS Appendix I; and this report Appendix 4
Consideration of alternative eradication methods: <ul style="list-style-type: none"> • Suggest there is overall support on LHI for the REP, although many do not support eradicating with brodifacoum by hand broadcast or aerial baiting • Use of bait stations across LHI needs to be seriously considered and assessed – more safer option and would be easier to implement • The REP should be delayed until more safer alternatives are available • Other alternatives need to be explored – less toxic rodenticides, rodent-proof fencing with a staged implementation, use of brodifacoum as per manufacturer's instructions 	Alternatives to brodifacoum considered in LHIB PER Section 3. Fencing considered in LHIB SIS Section 2.9.1.5. Alternative distribution methods considered in LHIB PER Section 3.4.3

<ul style="list-style-type: none"> What options for rodent control other than the use of anticoagulants have been considered? There is an increasing opposition to aerial baiting of uninhabited islands internationally and greater opposition can be expected on inhabited islands 	
The 'precautionary principle' should apply to the REP	Precautionary principle in relation to environmental damage is considered in LHIB PER Section 1.10
The number of rodents on LHI has been extremely exaggerated and some of the birds are causing more damage	Damage from birds not compared. Estimates are described in LHIB PER Sections 1.9, Appendix D1 and D2
There is a high risk of failure (50% to 90% quoted)	Likelihood of success considered in LHIB SIS Section 2.13 and LHIB PER Section 3.6
Environmental and agricultural risk: <ul style="list-style-type: none"> Risk mitigation strategies implemented by the US EPA Consequence of using brodifacoum on organic farms Risk of extinction of land and sea birds Effect on coral Impact on bees Risk to poultry and dogs 	<ul style="list-style-type: none"> Australian Government approvals in LHIB PER Section 7.10; other countries requirements mentioned in 5.2.2 of this report LHIB have informed they are not aware of registered organic farms on LHI Risks from rodent predation addressed in LHIB PER Section 1.9.1. Risk to bird species from REP addressed in Section 5.2.3 and 5.2.8 LHIB PER Section 5.2.10 LHIB PER Section 5.2.5 LHIB PER Section 10.2 and Appendix K. Management of domestic and farm animals is also discussed through Property management plans
The abundance of Kentia Palm seeds on LHI may impact on the success of the REP	Palatability of bait considered in LHIB PER Section 3.2, Appendix D1 and D2. Alternative food sources considered in LHIB SIS Section 2.13
Legal approvals and brodifacoum use: <ul style="list-style-type: none"> The proposed distribution method for brodifacoum is contrary to that mandated by the US EPA which has been developed to minimise possible ingestion by children and wildlife Legal status of using Pestoff20R contrary to manufacturer's instructions 	Australian Government approvals in LHIB PER Section 7.10; other countries requirements mentioned in 5.2.2 of this report
Liability: <ul style="list-style-type: none"> Liability should ill-health effects be observed due to exposure to brodifacoum There is no insurance coverage (or compensation) for the REP 	LHIB has advised they have insurance covering all legal activities (this would include the REP when all approvals received). Community has previously been provided with LHIB's insurance certificates
Costs and benefits: <ul style="list-style-type: none"> What are the expected, measurable benefits and costs of embarking on this program, now and in five years? Loss of income during and after the REP What are the risks/costs of doing nothing? 	LHI PER: biodiversity benefits and the risks of doing nothing are considered in Sections 1.9 and 3.1.3; biodiversity monitoring program described in Section 2.8; economic benefits in Section 10.1 and full economic report: http://www.lhib.nsw.gov.au/community/news/economic-evaluation-lhi-rodent-eradication-project
Community well-being: <ul style="list-style-type: none"> The proposed REP is cause anxiety and social division in the community The proposed REP is having an impact on the mental health of LHI residents 	Considered in Section 6.3 of this report
Water supply: <ul style="list-style-type: none"> Protecting rainwater supplies from poisoned (dead) rodents and birds Strategies for covering roofs and gutters, protecting rainwater supplies from pellets and dust 	Collection of dead rodents from settlement area listed in LHIB PER Table 3: Project Phases. Use of buffer zones and the Property Management Plans in the settlement area in LHIB PER Section 2.3.5 and 2.3.8

APPENDIX 4 ISLAND RODENT ERADICATIONS

Summary

This supplementary report provides a summary of available information on rodent eradication programs undertaken or proposed on islands.

In undertaking this report, OCSE consulted the most comprehensive compilation of historical and current invasive vertebrate eradication projects on islands, the Database of Island Invasive Species Eradications (DIISE, 2015). The DIISE attempts to compile all historical and current invasive vertebrate eradication projects on islands since the 1950's. Data includes island geography, target species, methods, outcomes, contact details and links to more information about each project.

Overview of island rodent eradication programs

Data on historical and current invasive eradication programs on islands was obtained from the Database of Island Invasive Species Eradications DIISE (2015). There have been 875 eradication programs specific to rodents on a total of 724 islands worldwide, with 645 (74%) of these attempts classified as successful across 577 islands. The majority of these programs were for black rat, brown (Norway) rat, polynesian rat and house mice. Many islands target more than one species of rodent through a single eradication program. The total number of programs includes eradication programs with multiple target species on 19 islands, which are listed separately as some species were successfully eradicated while others were not, or the status of one species was unknown. Of the 15 records where the status of all species has been declared, 87% involved a failure to eradicate house mice while successfully eradicating rat species.

Of the total rodent eradication attempts noted above, 749 of them used a toxicant as the primary method (with 68 trapping/hunting and 58 unknown/other). Only a few eradication programs were not a whole-island attempt (3%). Further details about eradication programs using toxicants are in Table 1. The majority of toxicant programs used a single method of deployment (e.g. aerial only). Only 53 programs using aerial baiting (as a primary or secondary method of bait broadcasting) were also reported to use bait stations and/or hand baiting. The success rate of the combination of aerial and other methods was 83% (44 successful programs out of 53) compared with 68% success for aerial alone (110 successful programs out of 161).

According to the database, 94% of the rodent toxicology eradication attempts have occurred on islands with 10 or fewer inhabitants. There have been 44 attempts using toxicants on 29 islands with greater than 10 inhabitants, 64% of these have succeeded in eradication and 23% are known failures.

On islands with greater than 10 inhabitants, aerial broadcast has been used as the primary technique for 18 programs, and is planned for Lord Howe Island. Bait stations have been used as the primary technique for 20 programs, with an additional trial/research program. Fewer programs used hand broadcasts as the primary eradication technique (3). The number of successes for aerial broadcast and bait station on inhabited islands is quite similar (13 and 14 respectively). There were more known failures for bait station attempts (6) than for aerial attempts (2).

Brodifacoum is by far the most common primary toxicant used, accounting for 546 (73%) of all eradication programs using toxicants. Of these programs 79% are known successes. For aerial baiting on inhabited islands, 17 of 18 attempts used brodifacoum, a further one on Lord

Howe Island is planned. Of these attempts, 13 were successful (76%), two failed (12%) and the rest are either in progress or to be confirmed.

When examined separately, there have been a total of eradication attempts for house mice. Of these, 71 have been declared successful, 26 have failed, and 14 are as yet unconfirmed (success rate of 73%; DIISE, 2015). There have been 428 eradication attempts for black rats, 316 of these attempts have been declared successful, 43 have failed and 69 are as yet unconfirmed (success rate of 88%; DIISE, 2015).

Table 1: Toxicant rodent eradication programs (DIISE, 2015)

	Overall No.	Primary baiting method No. (% of total)			
		Aerial	Bait station	Hand broadcast and piles	Other/unknown
Total attempts	749	212	290	210	37
Success	571 (76%)	151 (71%)	225 (78%)	172 (82%)	23 (62%)
Failure	86 (11%)	23 (11%)	40 (14%)	18 (9%)	5 (14%)
Other: planned/in progress/to be confirmed/incomplete/trial or research/unknown	92 (12%)	38 (18%)	25 (9%)	20 (10%)	9 (24%)
Primary toxicant					
Brodifacoum total	546 (73%)	194 (92%)	187 (64%)	155 (74%)	10 (27%)
<i>Success</i>	434	146	153	127	6
<i>Failure</i>	58	18	25	12	3
<i>Other</i>	56	30	9	16	1
Diphacinone	61	10	25	26	0
Bromadiolone	32	2	13	16	1
Pindone	18	0	18	0	0
Warfarin	11	0	8	3	0
Other/unknown	81	6	39	10	26
Human Population					
>10 inhabitants total	44 (6%)	19 (9%)	21 (7%)	3 (1%)	1 (3%)
<i>Success</i>	28	13	14	1	0
<i>Failure</i>	10	2	6	2	0
<i>Other</i>	6	4	1	0	1
<i>Brodifacoum used</i>	34	18	13	3	0
≤10 inhabitants total	705 (94%)	193 (91%)	269 (93%)	207 (99%)	36 (97%)
<i>Success</i>	543	138	211	171	23
<i>Failure</i>	76	21	34	16	5
<i>Other</i>	86	34	24	20	8
<i>Brodifacoum primary toxicant</i>	512	176	174	152	10

Repeat eradication attempts

Eradication programs on islands have recorded a higher number of successes rather than failures. Holmes et al. (2015) provides a detailed analysis of factors associated with failure, and reasons behind a higher failure rate in tropical islands.

Records from the Database of Island Invasive Species Eradications (DIISE, 2015) reveal that initial failures may be followed by a successful program. On 12 islands a successful eradication of a species using brodifacoum occurred after an initial failed attempt, also using brodifacoum (Table 2). While some of these subsequent attempts occurred more than a decade later, three were within two years of each other. Of the 12 islands, nine used aerial baiting for their most recent and successful program. In addition, nine other islands recorded a successful eradication following failure using methods other than brodifacoum baits in both attempts.

Table 2: Whole-island eradication successes after failure using brodifacoum, using data from DIISE (2015) unless otherwise indicated

Island	Species	Year/Status	Baiting methods
Crocus, Montebello Islands, Australia	black rat	1996 Failure 1997 Success 2001 Success ^a	Bait station Bait station Aerial
Hermite, Montebello Islands, Australia	black rat	1996 Failure 1999 Failure 2001 Success	Bait station Aerial Aerial
Primrose, Australia	black rat	1996 Failure 1997 Success 2001 Success ^a	Bait station Bait station Aerial
Low Cay, Bahamas	black rat	1999 Failure 2000 Success	Bait station Bait station
Bainbridge 1, Ecuador	black rat	2002 Failure 2011 Success	Bait station Aerial
Pinzon, Ecuador	black rat	1998 Failure ^b 2012 Success	Bait station/hand Aerial
Coppermine, New Zealand	Polynesian rat	1992 Failure 1997 Success	Bait station Aerial
Mokoia, New Zealand	house mouse	1996 Failure 1989 Failure 2003 Success	Aerial/hand Bait station Aerial/hand
Rakino, New Zealand	brown rat	1992 Failure 2002 Success	Bait station Bait station
Isabel, Mexico	black rat	1995 Failure 2009 Success	Bait station Aerial
Denis, Seychelles	house mouse	2000 Failure 2002 Success	Aerial Bait station
Palmyra, United States	black rat	2001 Failure 2011 Success	Bait station Aerial/hand

^a Lohr, Van Dongen, Huntley, Gibson, and Morris (2014)

^b Brodifacoum used as secondary toxicant

Successful long-term eradication requires ongoing mechanisms and monitoring to ensure reinvasion does not occur. Records from the Database of Island Invasive Species Eradications (DIISE, 2015) reveal that 43 islands plan to or have conducted another whole-island eradication program following an earlier program that was declared a success for the same species. This may be due to reinvasion or it may be possible that some of these initial ‘successes’ were incorrectly declared.

In order to avoid reinvasion, successful eradication generally requires a quarantine management system, which includes strict protocols for any goods or transport before departure and arriving on the island (Greenslade, Burbridge, & Lynch, 2013; Chevron Australia, 2014).

Current Agreed Best Practice (Pacific Invasives Initiative, 2016) recommends waiting two rodent breeding cycles to detect possible survivors before confirming whether the program was a success. In temperate environments this generally equates to two years, in tropical environments this is after one year (Keitt, Griffiths, Boudjelas, Broome, Cranwell, Millett, Pitt, & Samaniego-Herrera, 2015). It is recommended that monitoring and determination should use at least two independent and suitable detection methods (Russell, Towns, & Clout, 2008).

Rodent eradications on inhabited islands

To provide greater context for the HHRA report, rodent eradication programs on inhabited or seasonally inhabited/visited islands were examined in greater detail (Table 3). Each island is ordered by region, country, and then alphabetically. The OCSE assessed the quality of the data used by the DIISE (2015). Table 3 only includes DIISE data that could be independently verified. Additional references are included in the reference column.

The contents of all other columns are explained here:

Year: Year of eradication attempt. If two years are listed, this corresponds to an initial failed eradication attempt followed by a subsequent attempt.

Area: Total island plan area.

Population: Island inhabitation as reported in references collected from census data or online reports and sources, and when available, from the time period closest to the eradication program. Conservative estimates were made for islands that experience seasonal habitation.

Method: Rodenticide used and some detail about the concentration and application.

Target: Target eradication species: MM = *Mus musculus* (house mouse); RE = *Rattus exulans* (Polynesian rat); RN = *Rattus norvegicus* (Norway/ brown rat); RR = *Rattus rattus* (ship rat); RT = *Rattus tanezumi* (tanezumi rat). Some programs include other non-rodent species.

Status: Using DIISE eradication status codes: S = success; F = failure to remove all rodents; TBC = to be confirmed; P = planned; T/R = trial or research only.

Tropic: Tropical islands as defined by the UN Island Directory (UNEP, 2006).

Max elevation: Maximum elevation above sea level retrieved mainly from the UN Island Directory (UNEP, 2006), and indicated with superscript (^a) where obtained from ArcGIS (2016).

Natural features, land use: Relevant information where known on the terrain and land use that was considered in the eradication program.

Notes: Relevant information where known on HHRA and other risk management assessments, community consultation, and reasons for eradication success or failure.

Table 3: Rodent eradication programs from inhabited islands

Region: South-west and western Pacific

Island	Year	Area (km ²)	Population	Method	Target	Status	Tropic	Max elev. (m)	Natural features, land use	Notes	References
Broughton, NSW, Australia	2009	1.14	Up to 50 semi-permanent fishers	Aerial with hand baiting around buildings, brodifacoum, Pestoff Rodent 20R	RR, rabbits	S	No	90 ^a	Part of Myall Lakes National Park	30m exclusion zone around building precinct was baited by hand	Priddel, Carlile, Wilkinson, and Wheeler (2011)
Macquarie, subantarctic, Australia	2010-2011	129	13 - 35 staff during the eradication	Aerial and hand broadcast, brodifacoum, Pestoff Rodent 20R	MM, RR, rabbits	S	No	433	World Heritage and National Heritage listed, protected as a nature reserve. Research station occupied all year	Risk to staff was assessed as low in an EIS that included human health, community wellbeing and cultural heritage, with actions to address risks	Parks and Wildlife Services Tasmania (2009)
Mer, (Murray) QLD, Australia	2009-2012	4.59	485	Bait stations placed in settled or disturbed areas determined to have high density of target species, 9 rounds of baiting over 4 years	MM, RR	S	Yes	230 ^a	Fertile soil, densely vegetated	The majority (300) of residents expressed support for program	Department of the Environment and Energy (2016)
Viwa (Verata), Yasawa, Fiji	2006	0.6	100	Bait stations, hand broadcast, leg-hold trap and cage trap. Preliminary eradication done by residents, with support from specialists.	RE, cat, dog, cane toads	F for rats, S for other spp,	Yes	36 ^a	Farmland, plantation	Initial proposal to eradicate invasive cane toads was modified following consultation with residents to include cats, dogs, and rats	Saunders, Blaffart, Morley, Kuruyawa, Masibalavu, and Seniloli (2007)
Goat (Hawere), Hauraki gulf, New Zealand	1994 2005	0.09	No permanent inhabitants but open to the public	1994: bait station. 2005: trapping stations on 50x50m grid and bait station, brodifacoum	RR	S	No	14	In Haruraki Gulf Marine Reserve	Reinvasion after successful 1992 eradication	MacKay and Russell (2005); Statistics New Zealand pers comm.
Great Barrier, outer Hauraki Gulf, New Zealand	–	285	885	Undecided (subject to further research)	MM, RE, RR	P	No	621 ^a	In Haruraki Gulf Marine Reserve; farming, tourism	An island-wide questionnaire found 93% supported more research on the ecological and economic benefits of removing rats	Ogden and Gilbert (2011); Statistics New Zealand pers comm.

Island	Year	Area (km ²)	Population	Method	Target	Status	Tropic	Max elev. (m)	Natural features, land use	Notes	References
Rakino, outer Hauraki Gulf, New Zealand	1992 2002-2004	1.48	15 permanent residents	Brodifacoum in bait stations, 50 x 50m grid	RN	S	No	60 ^a	In Haruraki Gulf Marine Reserve; 75 dwellings, partially farmed, tourism	The program proceeded until no bait was taken from the stations, about 6 months	Bassett, Cook, Buchanan, and Russell (2016); Clout and Russell (2006); Great Barrier Island Environmental News (2016); Statistics New Zealand pers comm.
Rangitoto and Motutapu, Hauraki Gulf, New Zealand	2009	23.11 and 15.09	21, marine reserve, open to public	Aerial brodifacoum, Pestoff Rodent 20R	MM, RN, RR	S	No	260 and 114 ^a	The two islands are joined by a causeway. Rangitoto is a scenic and Motutapu a recreation reserve	Post baiting residue analysis found no brodifacoum in sea water or bivalve samples. Brodifacoum in low doses was detected in some non-target species	Fisher, Griffiths, Speedy, and Broome (2011); The Motutapu Restoration Trust (2016); Statistics New Zealand pers comm.
Burgess (Pokohinu), Mokohinau Islands, New Zealand	1990	0.56	No permanent inhabitants but open to the public	August 1990: Aerial brodifacoum, Talon 20ppm. October 1990: hand broadcast of Talon 50ppm and trapping. 1991: permanent bait stations and trapping	RE	S	No	52	Grazing occurred until the 1970s. The islands are now regenerating naturally, managed as a scenic reserve	Monitoring to determine whether the eradication was successful included: snap traps, searches for signs (faecal pellets, signs of feeding on fruit or scavenging). Non-target monitoring also conducted	McFadden and Greene (1994); Statistics New Zealand pers comm.
Kapiti, lower North Island, New Zealand	1996-1996	19.8	12, classed as an inhabited marine reserve	Aerial Broadcast approx 4 weeks apart and Hand Broadcast, Talon 7-20 bait containing 20ppm brodifacoum	RE, RN	S	No	521 ^a	Steep exposed slopes and cliffs on one side. Forest cleared for pasture, tourism. Nature reserve and marine reserve	Pre-baiting trials found many smaller (12mm) non-toxic baits got caught in the canopy. Following baiting, some non-target bird deaths recorded, monitoring showed losses would be recovered quickly; reef fish showed no evidence of negative affects	Empson and Miskelly (1999); Sinclair, McCartney, Godfrey, Pledger, Wakelin, and Sherley (2005); Statistics New Zealand pers comm.
Campbell (Motu Ihupuku), subantarctic New Zealand	2001-2003	113	No permanent inhabitants	Aerial broadcast, single aerial drop of 6 kg/ha (total of 120 tonnes of bait) with a 50% overlap of bait swaths, brodifacoum Pestoff 20R (20ppm)	RN	S	No	567	Farming and livestock grazing occurred until 1931. Managed as a nature reserve, World Heritage listed	Monitoring conducted with snap traps, gnaw sticks and trained dogs several times before declaring the eradication a success	McClelland (2011); Statistics New Zealand pers comm.

Island	Year	Area (km ²)	Population	Method	Target	Status	Tropic	Max elev. (m)	Natural features, land use	Notes	References
Stewart (Rakiura), Southern Islands, New Zealand	–	1,695 (entire island)	387	Brodifacoum Pestoff 20R or diphacinone bait stations on a grid. Initial pilot of removal of target species from 21.5-48km ² area proposed.	RE, RN, RR cat, possum, hedgehog	P	No	980	Agriculture and fishing industry. Contains Rakiura National Park (85% of the island)	Eradication has been undertaken on seven nearby islands in the same archipelago	Predator Free Rakiura (PFR) Governance Group (2015a); Predator Free Rakiura (PFR) Governance Group (2015b); Statistics New Zealand pers comm.
Pitcairn Island, Pitcairn	1997-1998	4.6	35	Hand broadcast, brodifacoum	1997: Cat, 1998: RE	F	No	347	Forest, shrubland	Eradication reported to have been opposed by residents due to competition for funding	Oppel et al. (2011)
Kayangel atoll, Palau	2011	1.12	188, approx. 50-60 at one time	Hand broadcast and bait stations, brodifacoum.	RR, RE	F	Yes	15 ^a	Coral atoll; 50 private residences, tourism	Four islands targeted for rodent eradication at the same time. Domestic wildlife contained during program	Critical Ecosystem Partnership Fund (CEPF) (2012); Matthews (2007); Oppel et al. (2011); (Matthews, 2007; Oppel et al., 2011); Palau Conservation (2011)
Wake, unincorporated US territory, Micronesia subregion	2012	6.96	200 military personnel	Aerial and hand broadcast, brodifacoum 28.3ppm	RE, Asian House Rat	F for RE, S for RT	Yes	10 ^a	Coral atoll; military base	Unclear why Asian House rats were eradicated but RE not. Post baiting monitoring suggests delayed mortality in some breeding females and emergence of young rats when bait was no longer available.	Griffiths et al. (2014); Oppel et al. (2011)

Region: Africa

Island	Year	Area (km ²)	Population	Method	Target	Status	Tropic	Max elev. (m)	Natural features, land use	Notes	References
Bird, Seychelles, Africa	1996-1998	1.01	37 staff, up to 40 visitors	Bait stations used a total of 200kg baits, followed by hand broadcasts every 10 days, brodifacoum. 12 permanent bait stations to prevent reinvasion	MM, RR, rabbit	S for RR and rabbits, F for MM	Yes	8	Flat coral island; tourism, privately owned	A feasibility study determined which baits to use and assessed risk to non-target species and bait take from non-target species. Higher concentrations of bait along coastal strip and in areas of cover such as under buildings	Seychelles National Bureau of Statistics (2002); Merton, Climo, Laboudallon, Robert, and Mander (2002); Plant Conservation Action group (2009)
Denis, Seychelles, Africa	2000, 2002	1.43	78	2000: Aerial, 2 pulses with a 9 day interval, brodifacoum, PestOff 20R. 2002: bait stations, brodifacoum	MM, RR, cat	2000:S for RR; F for MM. 2002: S for RR, MM	Yes	10 ^a	Flat coral island, managed partially as nature reserve; tourism, privately owned	2001: RR and MM were found. RR thought to have invaded, MM thought to have invaded or survived the eradication	Hill, Vel, Holm, Parr, and Shah (2002); Merton et al. (2002); Plant Conservation Action group (2009); Seychelles National Bureau of Statistics (2002)
Fregate, Seychelles, Africa	1995-1996 2000-2002	2.20	208permanent inhabitants	1995: Bait stations and hand broadcast in a grid; 2000: Aerial, brodifacoum	1995: RN, 2000: MM, RN	1995: F 2000: S	Yes	125 ^a	Granitic island; agriculture and tourism, privately owned	Control was attempted before the eradication program. Eradication was driven by the negative impact of RN on tourism. Summary of the eradication program provided in Merton et al. (2002)	Plant Conservation Action group (2009); Thorsen, Shorten, Lucking, and Lucking (2000); Merton et al. (2002); Seychelles National Bureau of Statistics (2002)
North, Seychelles, Africa	2003, 2005	2.01	148	Three (2003) or four (2005) aerial applications, hand broadcasting around hotel, permanent bait stations, brodifacoum (20ppm)	RR	2003: S. 2005: S	Yes	180 ^a	Granitic island; tourism and environmental restoration, privately owned	Eradication in 2003 thought to be successful but reinvasion occurred. Later programs used stricter protocols to avoid reinvasion	Plant Conservation Action group (2009); Seychelles National Bureau of Statistics (2002)
Tristan da Cunha, St Helena	–	98.5	285	Aerial and hand broadcast, brodifacoum	RR, MM	P	No	2,060	Remote, natural grassland; livestock, fishing and tourism	Eradication on hold, not all of the community was supportive. Improvements to control and biosecurity on Tristan and eradicate MM from nearby Gough Island are proceeding	Brown (2007); Oppel et al. (2011); Varnham, Glass, and Stringer (2011); Wolfaardt, Glass, and Glass (2009)

Region: South America

Island	Year	Area (km ²)	Population	Method	Target	Status	Tropic	Max elev. (m)	Natural features, land use	Notes	References
Alejandro Selkirk, Juan Fernández Archipelago, Chile	–	110	40 seasonal	Aerial broadcast, brodifacoum	MM, RN, RR, rabbits, feral cats	P	No	1,649	Forested, remote, rugged topography, Chilean National Park and UNESCO International Biosphere Reserve; fishing	Multi species approach to eradication of plants and animals, community largely supportive	Glen, Atkinson, Campbell, Hagen, Holmes, Keitt, Parkes, Saunders, Sawyer, and Torres (2013); Oppel et al. (2011); Saunders, Glen, Campbell, Atkinson, Sawyer, Hagen, and Torres (2011)
Robinson Crusoe, Juan Fernández Archipelago, Chile	–	47.9	674	Aerial broadcast, brodifacoum	Rat, cat	P	No	914	Forested, remote, rugged topography. Farmland, tourism (scuba diving)		Glen et al. (2013); Oppel et al. (2011); Saunders et al. (2011)
Floreana, Galápagos Islands, Ecuador	–	172	100	Aerial and hand broadcast of brodifacoum	RN, cat	P	Yes	640	Dry arid lowland and forested highland. Agriculture and conservation	Feasibility study assessed the impacts to human health, and mitigation eg restrictions on near shore fishing and consumption of agricultural products following baiting. Previous rat control in petrel colony	Galapagos Conservancy (2016); Island Conservation (2013); Nicholls (2013)
Isabela, Galápagos Islands, Ecuador	–	4,640	1,800	Aerial and hand broadcast of brodifacoum	RR, RN, MM	P	Yes	1,707	Formed from six shield volcanoes. Fishing, farming and tourism		Galapagos Conservancy (2016); Harper and Carrion (2011)
San Cristobal, Galápagos Islands, Ecuador	–	558	6,000	Aerial and hand broadcast of brodifacoum	RR, RN, MM, goats	P	Yes	896	Port town, large fishing fleet, airport	Previous rat control in petrel colony	Galapagos Conservancy (2016); Harper and Carrion (2011)
Santa Cruz, Galápagos Islands, Ecuador	–	986	12,000	Aerial and hand broadcast of brodifacoum	RR, RN, MM	P	Yes	864	Tourism and agriculture, airport	Previous rat control in petrel colony	Galapagos Conservancy (2016); Harper and Carrion (2011)

Island	Year	Area (km ²)	Population	Method	Target	Status	Tropic	Max elev. (m)	Natural features, land use	Notes	References
South Georgia, South Georgia and the South Sandwich Islands	2011-2015	3,717	Grytviken settlement 20-30 in summer, no permanent residents	Aerial broadcast and hand broadcast, brodifacoum 25ppm. Program was 3 stages due to topography, settlement baited during phase 1	RN, MM	TBC	No	2,934	Administration centre, scientific base, fishing and tourist ship stop. Marine protected area	Risk to human health (outlined in the EIA) was found to be very low in a well-planned and managed baiting operation	Government of South Georgia and the South Sandwich Islands (2017); South Georgia Heritage Trust (2010)

Region: North and Central America

Island	Year	Area (km ²)	Population	Method	Target	Status	Tropic	Max elev. (m)	Natural features, land use	Notes	References
Isabel Island, Gulf of California, México	1995, 2009	0.82	100, inhabited by fisherman for most of the year	1995: Bait stations, 50ppm brodifacoum. 2009: Aerial 25ppm brodifacoum pellets	RR, cat	S for cats, S in 2009 RR	Yes	–	Tropical forest	Initial failure was likely because of poor timing in relation to reproductive biology and food availability of the target species, and unanticipated levels of bait uptake by native land crabs	Aguirre-Muñoz et al. (2008); Oppel et al. (2011); Rodríguez, Torres, and Drummond (2006); Samaniego-Herrera, Aguirre-Muñoz, Rodríguez-Malagón, González-Gómez, Torres-García, Méndez-Sánchez, Félix-Lizárraga, and Latofski-Robles (2011)
San Benito Oeste, San Benito Archipelago, Baja California, México	2013	3.64	2 permanent, up to 70 seasonal inhabitants	Aerial broadcast	Cactus mouse	S	No	195 ^a	Desert ecosystem	Previous eradications: rabbits and goats in 1998; donkeys in 2005	Aguirre-Muñoz et al. (2008); Latofski-Robles, Aguirre-Muñoz, Méndez-Sánchez, Reyes-Hernández, and Schlüter (2014)
Grassy Key, Florida, USA	2006-2009	3.65	About 300 properties	Bait station and traps, zinc phosphide grain mix (2%)	Gambian giant pouched rats, RR	F	No	6 ^a	Coral island, 40% of island covered by residential properties	Research indicated small ranges in good habitat, with rats rarely leaving a property, some properties were not accessible; traps and stations were placed around perimeters of inaccessible properties, eradication still failed.	Witmer and Hall (2011)

Island	Year	Area (km ²)	Population	Method	Target	Status	Tropic	Max elev. (m)	Natural features, land use	Notes	References
Midway Atoll (Sand Island), USA	1996	4.86	20	Bait stations and traps, brodifacoum and bromethalin on 50m grid	RR	S	No	45 ^a	National Wildlife Refuge	The largest and only permanently inhabited island in the U.S with successful rat eradication. Monitoring to avoid reinvasion has continued	Hess and Jacobi (2011); U.S. Fish & Wildlife Service (2017); Northwestern Hawaii Islands Multi-agency Education Project (2002)
Palmyra, US minor outlying islands	1995 2001 2011	2.35	4–20 staff and scientists, no permanent residents	1995: 50ppm wax blocks, brodifacoum and bromethalin. 2001: Bait stations and hand broadcast, 100ppm bromethalin. 2011: Aerial and hand broadcast, brodifacoum 25ppm	RR	1995: F, 2001: F, 2011: S	Yes	2	25 small, heavily vegetated islets surrounding 3 central lagoons; National Wildlife Reserve	Report (2004) stated that resistance trails found some tolerance to brodifacoum, which they attributed to long-term rat control programs. During eradication, some native species held in captivity during eradication to avoid exposure	Howald et al. (2004); Island Conservation (2017); Williams, Smith, Conklin, Gove, Sala, and Sandin (2013)

Region: Europe

Island	Year	Area (km ²)	Population	Method	Target	Status	Tropic	Max elev. (m)	Natural features, land use	Notes	References
Giannutri, Tuscan Archipelago, Italy	2006	2.39	13	Bait stations, 50m apart brodifacoum, four applications	RR	S	No	46 ^a	Shrubland; part of the Tuscan Archipelago National Park	Studies on rat abundance on the island were used to determine bait density and application rates	Capizzi, Baccetti, and Sposimo (2016); National Statistics Institute Italy (2016)
Isle of Canna, Scottish Inner Hebrides, UK	2005-2008	13.17	15	Bait stations (> 4,300), 50m grid, diphacinone and bromadiolone	RN	S	No	210 ^a	Two semi-connected islands; open grassland, pasture; tourism, owned by National Trust of Scotland	Native mice were held in captivity during eradication to avoid exposure. Program included long-term monitoring and quarantine audit before declaring success	Bell, Boyle, Floyd, Garner-Richards, Swann, Luxmoore, Patterson, and Thomas (2011)
Lundy, Isles of Scilly, UK	2002-2004	4.82	28	Bait stations (>2,000), 50 x 50m grid, difenacoum 50ppm, over a one year period	RN, RR	S	No	143 ^a	Heath, grassland, difficult terrain; 23 tourist cottages, sheep farm	The program to eradicate RR faced opposition from animal rights campaigners	Appleton, Booker, Bullock, Cordrey, and Sampson (2006); Oppel et al. (2011); (Ellis, 2013)
Saint Agnes and Gugh, Isles of Scilly, UK	2013	1.05 and 0.37	85	Bait station, difenacoum, single bait application	RN	S	No	56 ^a	Islands joined by sandbar; agriculture and tourism	Feasibility study interviewed residents and examined impact on business and properties	Ellis (2013); Bell (2011)

APPENDIX 5 INCIDENTS OF EXPOSURE TO RODENTICIDES REPORTED TO THE NSW PIC DURING 2004-2015

Long Acting Anticoagulant (includes brodifacoum)

Year	Neonate (0-4 weeks)	Infant (4 weeks- 1 yr)	Toddler (1-4 yrs)	Child (5-14 yrs)	Adolescent (15-19 yrs)	Adult (20-74 yrs)	Elderly (>75 yrs)	Unknown	Grand Total
2004	0	44	273	13	2	37	0	10	379
2005	0	55	297	12	4	43	1	8	420
2006	0	50	320	13	3	33	1	10	430
2007	0	46	294	16	5	32	1	11	405
2008	0	61	334	28	8	40	0	9	480
2009	0	75	338	44	7	61	1	9	535
2010	0	37	315	37	5	29	0	16	439
2011	0	42	334	26	4	31	1	16	454
2012	0	26	236	21	5	29	0	17	334
2013	0	29	168	20	1	29	0	9	256
2014	0	51	220	9	2	30	1	1	314
2015	0	32	219	7	3	55	1	0	317

Anticoagulant (warfarin)

Year	Neonate (0-4 weeks)	Infant (4 weeks- 1 yr)	Toddler (1-4 yrs)	Child (5-14 yrs)	Adolescent (15-19 yrs)	Adult (20-74 yrs)	Elderly (>75 yrs)	Unknown	Grand Total
2004	0	34	227	6	6	43	0	7	323
2005	0	34	252	11	4	37	1	2	341
2006	0	34	227	8	7	35	0	17	328
2007	0	19	198	10	1	32	0	5	265
2008	0	30	198	11	5	34	0	13	291
2009	0	25	184	10	5	22	0	8	254
2010	0	19	194	8	2	18	1	9	251
2011	0	24	180	10	1	15	0	11	241
2012	0	12	119	6	0	9	0	5	151
2013	0	15	142	10	3	27	0	5	202
2014	1	18	88	5	0	21	0	0	133
2015	0	12	49	1	1	11	0	0	74

Rodenticides other/unknown

Year	Neonate (0-4 weeks)	Infant (4 weeks- 1 yr)	Toddler (1-4 yrs)	Child (5-14 yrs)	Adolescent (15-19 yrs)	Adult (20-74 yrs)	Elderly (>75 yrs)	Unknown	Grand Total
2004	0	13	55	1	1	21	0	2	93
2005	0	12	61	1	0	13	0	5	92
2006	0	19	82	7	3	13	0	5	129
2007	0	17	86	7	1	25	1	6	143
2008	0	23	108	8	2	30	1	5	177
2009	0	28	127	9	1	38	0	8	211
2010	0	16	162	11	3	31	0	8	231
2011	0	21	188	6	1	40	1	13	270
2012	0	31	173	10	2	25	0	11	252
2013	0	27	164	12	3	30	0	5	241
2014	0	23	113	6	1	33	1	1	178
2015	0	28	122	15	2	28	0	1	196

APPENDIX 6 SUMMARY OF EMERGING TOOLS AND TECHNIQUES FOR RODENT ERADICATIONS

The following table is a summary of recent information on emerging tools and techniques for rodent eradication obtained primarily from a paper on new eradication tools (Campbell et al., 2015) unless noted otherwise. Other references include the paper commissioned specifically for this report (see Swegen et al., 2017) updated with additional information including examples of specific applications where available.

It must be emphasised that this list is not an exhaustive list of all technologies; rather it is mainly a summary of those identified as available or in development, recent and promising from these two references.

Technology or technique	Description	Advantages	Disadvantages	Commercialisation
Toxic agents				
Norbormide (prodrug form)	Reformulation of the existing but infrequently used rodenticide norbormide (non-anticoagulant rodenticide) to delay action and increase palatability.	Other mammals and birds less sensitive than rats therefore it could be used near people, pets and other species.	Rattus-specific only (not mouse), effect on reptiles, amphibians, snails and other invertebrates unknown, trials show that target organism mortality <100%.	Approx. 5 years before potential commercialisation. Still in development.
RNA interference	Ribonucleic acid (RNA) interference selectively inhibit target gene expression – can be applied selectively to target specific life function.	Can be delivered orally, rapid research and development occurring in a number of fields (agriculture, human disease), extremely species specific.	Socio-political acceptance may be low due to similarities between genetic engineering and nanotechnology, many techniques protected by patents, persistence and fate in the environment unknown.	Approx. 5 to 10 years before potential commercialisation. Still in development. The only development of an RNAi vertebrate toxicant that the authors were aware of was for the sea lamprey (<i>Petromyzon marinus</i>).
Fertility control (immunocontraception and genetic mutation)				
Virus vectored immunocontraception	Immunisation triggers a response where the immune system of an organism attacks the reproductive cells resulting in sterility. The virus would be delivered aerially via a food pellet (U.S. Fish & Wildlife Service, 2013).	Humane and likely to be environmentally benign, the virus is self-spreading therefore less labour intensive and possibly cheaper than other methods and could be used at large scales.	A genetically modified vector is required, irreversible, potential for development of host resistance, difficult to control vectors once released, potential for transmission of animal infectious agents to humans, socio-political controversies.	Approx. 5 to 10 years before potential commercialisation. Whilst research is being conducted in the U.S. into this technology for rats (U.S. Fish & Wildlife Service, 2013), there are no immediate prospects for a commercially available rodent immunocontraceptive since no registered products exist either in the U.S. or elsewhere at present.

Technology or technique	Description	Advantages	Disadvantages	Commercialisation
Immunocontraceptives targeting gamete production	Gonadotropin-releasing hormone (GnRH) vaccines cause infertility by inhibition of ovarian and testicular function (Swegen et al., 2017).	GnRH vaccines have been used with reasonable success in temporary fertility control of domestic dogs (Swegen et al., 2017).	The use of GnRH vaccines in wild animals is limited due to practicality of administration and limited duration of efficacy (Swegen et al., 2017).	Several research groups including the CSIRO have been conducting research into GnRH for a number of years (Swegen et al., 2017).
Immunocontraceptives targeting gamete function	Gamete-function vaccines target the zona pellucida (ZP) causing infertility by preventing penetration of the sperm with the egg (Swegen et al., 2017).	ZP vaccines have some advantages over GnRH vaccines including a small delivery volume and the preservation of normal reproductive behaviour (Swegen et al., 2017).	The inability to deliver ZP other than by injection inhibits its efficacy in wild populations (Swegen et al., 2017).	Unknown.
Transgenic rodents	The most promising potential genetic technique is the 'daughterless' approach where genetically-modified males carry transgenes that don't produce daughters or induce females to develop as sterile males. This reduces female numbers so the population dies out.	Species specific, non-toxic, humane, can be designed to suit specific requirements and financial investment.	Socio-political controversies regarding release of genetically modified organisms, unpredictable survival of released mice, might need multiple releases, development and on-going costs, the same transgenic system may not be usable in all situations.	Approx. >2 years to field testing based on available biomedical technologies.
Gonadotoxicants causing permanent infertility	Causes target animals to become permanently infertile once they have consumed the effective dose (Swegen et al., 2017).	Can cause permanent sterilisation in both females and males, humane, non-toxic (Swegen et al., 2017).	Used to reduce populations over time rather than eradicate them, individuals need repeated intake to build up the required dose, each individual required to access baits to become infertile, chemical used may not be rodent specific, dispensed via bait stations therefore difficult to obtain complete coverage in some terrain (Swegen et al., 2017).	Restricted availability. ContraPest® (Senestech, 2016), a product designed for rat control using 4-vinylcyclohexene diepoxide (VCD) was registered and approved for use in the USA in 2016. It entered the registration process with the APVMA in 2008; however its current status is pending (Swegen et al., 2017).
Gonadotoxicants causing reversible infertility	Interferes with sperm function, eg ornidazole (a common antibiotic, Swegen et al., 2017).	Several compounds have shown promise in rodent trials inducing complete temporary infertility via oral administration (Swegen et al., 2017).		

Technology or technique	Description	Advantages	Disadvantages	Commercialisation
Other				
Crab deterrent in baits	A chemical deterrent to inhibit bait consumption by land crabs without deterring rodent consumption.	Reduce or eliminate land crab interaction with rodenticide bait, a significant contributor to unsuccessful eradications in tropical islands.	Nil.	No current known research on developing a product, although it is possible a known compound could be applied as a crab deterrent.
Prophylactic treatment for protection of non-target species	Applying a controlled-release vitamin K1 (antidote for anticoagulant rodenticides) slow release system such as an implant in non-target animals.	Labour and stress on the non-target species less than captive holding or translocation, disease and other risks avoided.	Labor intensive, difficult to trap and treat non-target animals. Many unknowns including: species variation in drug absorption rates, required dosages and tissue reactivity to implants, particularly for island endemic species.	Approx. 1-3 years before potential commercialisation.
Drones or unmanned aerial vehicles (UAVs)	Record high resolution imagery day or night via infra-red cameras with pre-programmed flights, for animal detection or the delivery of baits.	Reduced on-ground labour and therefore cost, available in a range of sizes.	Gaining operating permissions can be difficult, some countries don't permit use to deploy pesticides, the size and type of UAV's likely to be used are limited to low wind conditions.	Approx. <5 years expected to be adopted for aspects of REPs.
Species-specific self-resetting traps and toxicant applicators	Species specific traps and applicators including a self-resetting device delivering baits, and a spray system that relies on the grooming behaviour of the target animal for toxin ingestion.	May be used in areas where bait stations or broadcast techniques are considered inappropriate, protect non-target species, reduced risk of target species receiving a sub-lethal dose, device can remain active in the field for extended durations.	Insufficient as the only method in an REP - ideally limited to exclusion areas or potential reinvasion points; long-life attractants and toxicants (if used in trap) required.	Traps available. Approx. 2-4 years before potential commercialisation of toxicant applicators.
Detection probability models	Computer modelling to deliver more accurate detection of survivors and confirmation of a successful eradication.	Can be adapted for use in current projects, incorporating digital data collection and automated analyses will reduce costs and increase accuracy.	Requires appropriate detection methods with replication and statistical rigor.	Available