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 subpopulations. 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 14Cbrodifacoum 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 $\mu q/q$ and 0.07 $\mu q/q$ 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 ug/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 adiacent 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.

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 quidance (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 quidance 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 $9.6x10^{-6}$ 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 9.6x10⁻⁶ 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 $\mu q/q$, a water concentration of 0.01 $\mu q/L$ (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 worstcase scenario may result in 10% of pellets accidently 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 x 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 accidently 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 a*l (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.

- 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 \bullet 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.

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

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

$$
C_{aquifer} = \frac{CL_{exposure\ unit}}{DAF}
$$

Table 8 **ASTM (2010) Equilibrium Partitioning Model Equation Parameters**

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

The $\mathbf{0}_{\text{WS}}$ and \mathbf{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 grams per cubic centimetre $(q/cm³)$. 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 $g/cm³$.

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 litres per kilogram (L/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 g/cm³ range from approximately 50 g/kg to 175 g/kg. The lower end of the range (50 g/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 ($\frac{6}{5}$ = 298.15 - conversion of 25 $\frac{6}{5}$ 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 m^2 , 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*…".

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

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**

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 soilto-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'**

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

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 $1/400^{th}$ 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**

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

LHI exposed to brodifacoum

Percent of seafood caught locally from

Vegetable ingestion

Fruit ingestion rate

Seafood ingestion

rate (kg/day)

LHI exposed to

brodifacoum

rate (kg/day)

 (kg/day)

Toddler

 $1%$

 0.095

0.178

 0.011

 $(2-3 \text{ years})$

Recommended average daily intake of vegetables for a toddler (2-3yrs), school child (9-13 years) and adult (≥ 19 years) (enHealth, 2012; Table $4.4.2$).

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.

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)

 0.259

 0.216

0.026

Pregnant

Female

 1%

 0.224^{i}

 0.132

 0.026

School Child

 $(8-11$ years)

 $1%$

 0.156

0.157

 0.015

Exposure frequency Site-specific assumption based on LHI's knowledge of daily activity 20 20 20 20 to surface water patterns. Assumes brodifacoum surface concentrations do not reduce (days/year) overtime, which is a conservative assumption. Exposure time to Site-specific assumption based on LHI's knowledge of daily activity surface water 0.5 0.5 0.5 0.5 patterns. (hours/day)

 $4.4.3.5$).

Notes:

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 $a)$ 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,
- Average mean weight for male and females ≥18 years, Table 2.2.1 (enHealth, 201b2).
-
- e) Recommended mean water intake for a 2-3 year old child, Table 4.2.5 (enHealth, 2012b). 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 ve
- 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 (HO $\lt 1$), 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

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

Inhalation Pathways (dust)

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

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:

Hazard Index (HI) = Σ 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 anticoaqulant 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 HOs 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 noeffect standard. Accordingly, no specific amount of acute pellet ingestion will be characterised to be safe. However, interested adults, particularly parents and quardians 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

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 = Σ HQ)*	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 EUderived 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 accidently 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**

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 quardians 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 quardians 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.

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

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**

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)

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

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

Photo 7: Lord Howe Island Central School

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

Photo 9: Lord Howe Island Bowling Club green

Photo 10: Sports ground on Lagoon Road

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

Photo 12: View of Blinky Beach, looking south

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

Photo 14: View of Kings Beach, looking north

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

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)

Photo 19: Rainwater tank with 'first flush' system

Photo 20: Groundwater filtration unit owned and operated by LHIB

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

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

Photo 24: Commercial Nursery owned by 'Kentia Fresh'

Photo 25: Waste management facilities, looking north

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

Photo 27: Fish population at Ned's Beach

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

Photo 29: Soldier Creek, looking north

Photo 30 Old Settlement Creek, looking south west

APPENDIX C RISK ASSESSMENT ALGORITHMS

Appendix C

Risk Assessment Algorithms

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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)

Soil Ingsetion Intake $\left(\frac{mg}{kg}~day\right) = \frac{Cs \times 1Rs \times CF \times FI \times EF \times ED}{BW \times AT}$

1.2 Incidental Groundwater Ingestion (US EPA, 1989)

Groundwater Ingestion Intake $\left(\frac{mg}{kg}~day\right) = \frac{Lw \times 1Rw \times CF \times EF \times ED}{BW \times AT}$

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

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

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.

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

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:

Contact Intake $\left(\frac{mg}{kg}~day\right) = \frac{D A event \times EF \times EV \times ED \times SD}{BW \times AT}$

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

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

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:

 $D A event = Kp \times Cw \times t event$

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

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)

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

Tuber Crops

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

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*G*_{tuber} (mg/kg fw plant per mg/kg dw soil) = $\frac{k_1}{k_2 + k_a}$

Where:

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

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

$$
3600D_{water(W^{7/3}/\rho_p)}
$$

$$
k_2 = \frac{23(1 - K_{pw})}{R^2}
$$

Green Vegetables

 CF_{green} (mg/kg fw plant per mg/kg dw soil) $= (10^{0.95 \log Kow - 2.05} + 0.82) \times (0.784 \times 10^{-0.434 (\log Kow - 1.78)^2 / 2.44}) \times (\frac{\rho_s}{\theta_{ws} + (\rho_s, K_{oc}, F_{oc})})$

Tree Fruit

 CF_{fruit} (mg/kg fw plant per mg/kg dw soil) $=\frac{0.001\times (M_fQ_{fruit}DM_{fruit})\left(\frac{C_{stem}}{K_{wood}}\right)/M_f}{C_{soil}}$

Where:

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

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

Table C2 Variables Description for Estimation of Chemical Intakes

K_{oc} organic carbon-water partition coefficient for the contaminant, $cm³/g$ (compound-specific) F_{oc} unitless fraction of organic carbon in the soil unitless octanol-water partition coefficient, (compound-specific) Kow W root water content, (assumed equal to the default of 0.89) g/g root lipid content on a mass basis, (assumed equal to the default of Ē q/q $0.025)$ plant root density, (assumed equal to the default of 1) $q/cm³$ $\rho_{\rm p}$ unitless first order growth rate constant, per day (assumed equal to the K_g(root crops) default of 0.1) first order metabolism rate constant, (per day) (assumed equal to unitless K_m the default of 0) **RV** $cm³$ root volume, (assumed equal to the default of 1000) unitless rate of chemical flux into the potato, (per hour) $k₁$ rate of chemical flux out of the potato, (per hour) $k₂$ unitless $k_{\text{g(tuber crops)}}$ 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, organic carbon-water partition coefficient for the contaminant, Koc $cm³/g$ (compound-specific) m^2/s chemical diffusion coefficient in water, (compound-specific) **D**_{wate} $q/cm³$ potato tissue density, (assumed equal to the default of 1) $\rho_{\rm p}$ R radius of the potato, (assumed equal to the default of 0.04) m water content of potato, (assumed equal to the default of 0.79) W g/g Kpw $cm³/g$ equilibrium partition coefficient between potato and water unitless fraction of carbohydrates in the potato, (assumed equal to the f_{ch} default of 0.209) lipid content of potato on a mass basis, (assumed equal to the L g/g

default of 0.001)

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Table C3 Chemical Lipophilicity Table for Deriving Kch

2 References

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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

APPENDIX E SENSITIVITY ANALYSIS

Appendix E Sensitivity Analysis
Human Health Risk Assessment Lord Howe Island, Proposed Rodent Eradication Program

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Notes:

a) 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). $b)$

Mean surface area for hands only for a 2-3 year old child (enHealth, 2012; Table 3.2.5) \mathbf{c}

 d 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) e)

Sediment adherence factor for a child playing in sediment with contact via hands, arms, feet and legs (enHealth, 2012; Table 3.3.5) f

 q) 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) h)

i) 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 $j)$ 1 pellet/2 $m²$ (Section 6.1.4).

APPENDIX F RODENT ERADICATION PROGRAM FIGURE

Date Created: 3/09/2016

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 \bullet health effects need to be explored
- The HHRA needs to consider the 2014 opinion of the European Chemicals Agency \bullet 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 aguatic organisms and subsequent bioaccumulation and risk to \circ human health from eating seafood
	- The survival of brodifacoum in organisms, sediments and soil and its Ω subsequent accumulation up the food chain
	- o 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 Ω **autters**
	- o All locally produced food- milk, meat, eggs, vegetables and fruit
	- o Ingestion of pellets by children
	- Exposure to other vulnerable groups including children, the elderly, pregnant Ω women and those taking medications likely to interact with brodifacoum
	- \circ 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.

APPENDIX 4 ISLAND RODENT ERADICATIONS

Summary

This supplementary report provides a summary of available information on rodent eradications 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 eradications

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 eradications 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 eradications 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)

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

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

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 wholeisland 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); $RN = R$ attus norvegicus (Norway/ brown rat); $RR = R$ attus rattus (ship rat); $RT = R$ attus 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 $(^\circ)$ 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

Region: Africa

1.6

 \sim \sim

Region: North and Central America

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

Long Acting Anticoagulant (includes brodifacoum)

Anticoagulant (warfarin)

Rodenticides other/unknown

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.

Appendix 5

Assessment of human health concerns

- 1.1 Whilst human health is the primary responsibility of other state and Commonwealth agencies the Department considered human health issues as part of the assessment of socio-economic matters.
- 2. Brodifacoum is an acutely toxic substance that has the potential to cause toxicity and possible death through internal bleeding. It is an anticoagulant that prevents blood clotting by blocking production of Vitamin K which is vital to the clotting process. As clotting factors are used by the body, more cannot be made if there is no Vitamin K. Hence Vitamin K is an effective antidote to the effects of Brodifacoum.
- З. Brodifacoum can be harmful to humans through four pathways:
	- · direct ingestion of baits
	- · ingestion of contaminated food
	- . inhalation of Brodifacoum-laden dust
		- · absorption of Brodifacoum through the skin.
- 4. On LHI, the only pathway that poses a significant health risk is the direct ingestion of Brodifacoum baits by small children. Toxikos identified that the most important exposure pathway of Brodifacoum for humans is direct ingestion of bait pellets picked up off the ground. However, substantial quantities would need to be ingested to have any impact and with toxic signs apparent several days before the onset of any life threatening effects the toxicity of Brodifacoum is easily treated with Vitamin K.
- 5. The final PER notes that the low application rate, the inconspicuousness of the green pellets, and the relatively large amount of bait needed to pose a serious health risk (given the low concentration of Brodifacoum), combine to make accidental poisoning unlikely. The final PER concludes that the slow-acting nature of the poison and the availability of an effective antidote, mean that baiting poses negligible risk to the community.
- 6. Several studies cited in the final PER concluded that many of the potential human exposure pathways to Brodifacoum will not occur due to proposed management practices during and after the commencement of baiting e.g. removal from LHI or penning of poultry and cattle, isolation of dairy cows from exposure. Toxikos concluded that other direct and indirect exposure pathways pose negligible risk for human health.
- 7. LHIB has undertaken to inform all residents and visitors about the rodent baiting program. including the parents of young children who might be tempted to pick up and consume bait pellets.
- The final PER cites a number of studies and assumes that the maximum amount of fine 8. particles (<2mm) from aerial application of Brodifacoum will be 150g as delivered in bags plus 330g produced by mechanical abrasion in the hoppers during dispersion. Total fine particles being 480 g (rounded up to 500 g) - approximately 2% of the total bait content.
- 9. This equates to 240 mg/ha of Brodifacoum at the proposed application rate of 12 kg/ha bait (first drop) and concentration of 20 mg/kg Brodifacoum (20 ppm). If 2% of this 240 g/ha is fines (<2mm) this equates to 4.8 mg/ha (4.8 g/10000m2) Brodifacoum dust. At a drop height of 50m this equates to 0.0000096 mg/m3 or 0.0000096 ug/L Brodifacoum dust in the air column. Fine particles in the air column are expected to settle on the ground reasonably quickly.
- 10. According to the final PER, the occupational exposure limit applied to protect workers from the effects of Brodifacoum during manufacture of rodent bait is 0.002 ug/L or (2 µg/m3). Thus the maximum estimate of Brodifacoum in inhalable particulates in air during aerial broadcasting is orders of magnitude lower than the concentration used to protect workers, which the final PER considers presents negligible risk to the environment.
- 11. Consideration was given to adding a bittering agent (such as Bitrex which is added to commercially available rodenticides containing Brodifacoum) to the bait to make pellets unpalatable to children. LHIB decided not to add bittering agent because it is likely some rats and mice will not consume bait containing a bittering agent.
- 12. The Toxikos Human Health Risk Assessment (2010) recommended that in addition to the mitigation measures outlined in the draft LHI Rodent Eradication Plan residents should not consume the livers of fish that have been caught within 200m of the shore line until 6 months after the last bait broadcast, rainwater in household tanks should be tested and wild ducks should not be eaten.
- 13. These matters are generally outside the scope of the EPBC Act but the Department understands that they are being considered by the LHIB and the NSW Government. A human health risk assessment was undertaken by the NSW Chief Scientist and Engineer (Appendix 4 to the Recommendation Report). A copy of the report and will made available to LHI residents and the Department.
- 14. The Review on the Human Health Risk Assessment (HRAA) for the Lord Howe Island's proposed Rodent Eradication Program by the NSW Chief Scientist and Engineer assessment looked at potential exposure pathways of Brodifacoum to humans, including through soil, air (dust), sediment, surface water, tank water and 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.
- 15. A quantitative risk assessment of these exposure pathways and population groups concluded that exposure to Brodifacoum from all potential sources is below those likely to result in adverse health effects. The HRAA also assessed potential exposure due to ingestion of pellets and found that ingestion of one or two pellets by a child is unlikely to result in observable anti-coagulant effects.
- 16. Brodifacoum baits are already widely used within the settlement, and large quantities of warfarin bait are used at bait stations. Many of these stations are readily accessible, and pose a risk to humans, particularly children. Residents are therefore familiar with the risks of consuming and handling rodenticides. According to LHIB, residents will be provided with information about the hazards associated with Brodifacoum.
- 17. Children at the island's school will be informed about the operation and how they should behave around the toxic bait. Residents will be informed of the date of baiting well in advance, and will be issued with reminders closer to the time. Residents will also be kept informed of progress and will be notified when baits have disintegrated and there is no further risk of poisoning. A successful eradication will end the current use of rodenticides. thereby removing the risks to human health posed by the ongoing use of rodenticides and rodents.
- 18. The Department notes that the hospital will have supplies of vitamin K to treat anyone who ingests bait.
- 19. The Department reviewed a case study that was undertaken following the spillage of 18 tonnes of Brodifacoum cereal pellet bait into the tidal zone near Kaikoura on the south island of New Zealand on 23 May 2001 following a road accident. This case study is relevant to LHI where it is possible humans could consume fish or shellfish containing Brodifacoum or swimmers, snorklers and scuba divers could be effected by Brodifacoum pellets that fall or are washed into the ocean in sufficient concentrations.
- 20. Immediate monitoring was undertaken because of the importance of the area for human food collection and the lack of information at the time regarding the toxicity and residual persistence of Brodifacoum in marine species.
- 21. The report states that initial high environmental Brodifacoum concentrations in the immediate locality were probably sufficient to cause mortality of some invertebrates and fish, however, no dead fish were found and mortality would have been extremely difficult to measure in these mobile animals. Brodifacoum residues in the sea water and sediment declined to below detectable concentrations within 3 and 9 days respectively.
- 22. Residues in shellfish including edible mussels and paua took up to 31 months to decline to concentrations below the minimum lethal dose and therefore to acceptable levels for human consumption. This persistence of Brodifacoum was thought to be due to a combination of prolonged half-life in these invertebrates and re-exposure of the invertebrates to Brodifacoum in the highly wave exposed and dynamic tidal marine environment.
- 23. These issues will be addressed in the approval from the Australian Pesticides and Veterinary Medicines Authority (APVMA) in the form of a "Minor Use Permit" (for use of the toxin for the LHI rodent eradication program) which is required under the Agricultural and Veterinary Chemicals Code Act 1994. As the active constituent (Brodifacoum) is registered for use in Australia by the APVMA and therefore has established regulatory standards, a Limited Level Environmental Assessment is applicable. The Limited Level Environmental Assessment considers the of Brodifacoum fate in the environment (soil, air and water) environmental toxicology, bioaccumulation and potential impacts to all species present.
- 24. The NSW EPA is responsible for ensuring that the LHIB complies with the conditions specified in the minor use permit issued by the APVMA. The NSW Chief Scientist and Engineer also conducted a review of the potential impacts of the proposal on human health (Appendix 4).
- 25. The Department notes the high rainfall on the island and the importance of fresh water for a range of island inhabitants. However, once the bait pellets have disintegrated Brodifacoum will bind strongly to soil and sediments, be largely bio-unavailable and unlikely to affect lower order tropic levels. The chemical however has a long half-life in soil and its persistence in the volcanic soils of LHI has not been measured. Brodifacoum is also highly insoluble and therefore unlikely to be transported in waterways if not bound to sediments.
- 26. According to the LHIB, Brodifacoum's suitability and efficiency in eradicating rodents has been proven and it has been used on islands with human populations (e.g. Fregate, Laucala and Denis islands). The Island Eradication Advisory Group (worldwide eradication advisors) confirm that Brodifacoum is the most efficient poison for rodent eradications. The Department agrees with this conclusion.

Appendix 6

Background information on rat eradication programs

- Invasive rodents (rats and house mice) are the main cause of extinctions and ecosystem 1. changes on islands because they are omnivorous and affect plants, invertebrates, reptiles, mammals and birds. Invasive rodents occur on over 80% of the world's major islands.
- In response to the negative impacts of invasive rodents on island species and their 2. ecosystems, systematic techniques for eradicating rodents from islands were developed in New Zealand over 30 years ago. Rodents can now be eradicated from larger and biologically complex islands, and rodent eradication has become a major contributor to the prevention of extinctions and restoration of island ecosystems.
- A guide for best practice to maximise the likelihood of successful eradication was produced 3. by the New Zealand Department of Conservation, and recommends that two applications of bait are made about three weeks apart, to ensure that any rodents surviving the first operation will encounter pellets from the second. It is likely that some juvenile rats will emerge from nests some days after the first baiting is conducted and will not encounter baits unless a second bait drop is undertaken. To minimise the risk of gaps in bait coverage, flight lines overlap by 50%.
- LHI is located at latitude 31.5 degrees south. According to DIISE, few attempts have been 4. made to eradicate rodents on inhabited islands at a similar latitude to LHI in either the southern or northern hemisphere. In 1997/98 attempts to eradicate rodents on Pitcairn Island failed (latitude 27.1, area 460ha and population 68). The majority of aerial rodent baiting operations on uninhabited islands at latitudes within 25 and 36 degrees south and 25 and 35 degrees north appear to have succeeded, with some notable failures such as at Henderson Island (3730ha) near Pitcairn Island in 2011.
- In the northern hemisphere, an attempt to eradicate rodents using bait stations on Grassy 5. Key Florida (latitude 24.7, area 365ha and population 974) failed in 2009. Following completion of the Grassy Key baiting program the capture of Gambian rats steadily declined, but months later were still being captured or detected. An adult female was captured and fitted with a radio-collar. This individual rarely left a parcel of private property that the owners had denied the eradicators access to. Six private properties were off-limits to the eradicators and the article concluded that it is likely this is the main reason why the eradication effort was protracted (Source an article by Gary Witmer et al from the US Department of Agriculture located at

http://digitalcommons.unl.edu/cgi/viewcontent.cgi?article =2350&context=icwdm_usdanwrc&sei-redir=1&referer=http%3A%2F%2Fwww.bing.com %2Fsearch%3Fq%3Dgrassy%2Bkey%2Bflorida%2Brodent%2Beradication%26qs%3Dn% 26form%3DQBRE%26sp%3D-1%26pq%3Dgrassy%2 Bkey%2Bflorida%2Br%26sc%3D0-20%26sk%3D%26cvid%3DC1400FF24CAF4189 BEB4896DF5762766#search=%22grassy %20key%20florida%20rodent%20eradication%22

- The Department notes the relevance of the failure at Grassy Keys in relation to reports that 6. some LHI residents will not allow rodent baiting to occur on their properties and will deny access to eradication staff.
- The possibility of rodents persisting on some properties and leaseholds is addressed by 7. proposed condition eight that requires the LHIB to maximise the likelihood of eradicating rodents on the LHIG by using their best endeavours to ensure that rodent baiting is conducted on all properties and leases on the LHIG.
- If the eradication program fails to eradicate rats and mice on LHI any benefits deriving from 8. a reduction in rodent populations (ie the vast majority of the population killed, a few individuals remaining as occurred on Henderson Island) would be short-term, probably less than two years.
- 9. Any temporary benefits could be negated by an irruption of rodent numbers as they recovered. There could be a temporary population boom before the rodent population stabilises to a sustainable level. Such an irruption occurred on Tristan de Cunha in 1885, three years after rats arrived on the island, causing potato crop failures and severe short term effects on biodiversity.
- 10. If the eradication program succeeds in removing rats but not mice, the benefits will not be as great as if both species were successfully removed. Mouse populations will increase, causing greater damage than they currently do, including increased impacts on the island's ecology. However, it is unlikely mice would evolve to become significant predators of seabird chicks, as they have done on Gough Island. The absence of other mammalian predators and competitors on the island, meant that mice expanded their niche and attacked seabird chicks. It is unlikely that such behaviour would also evolve on LHI in the absence of rats.
- 11. Eradication of rats on LHI could contribute to the removal of mice in the longer term. The failure to eradicate mice in some rat-mouse eradication programs may be due to interactions between the species. Rats may prevent mice from accessing the bait.
- 12. According to the Guidelines for eradication of introduced mammals from breeding sites of ACAP-listed seabirds (ACAP being the Agreement on the Conservation of Albatrosses and Petrels) by 2007, rodents had been eradicated from at least 284 islands world-wide, most of which were relatively small (<100 ha). The target species were mainly black rat (159 islands) and Norway rat (104 islands) and to a lesser extent, kiore (Pacific rats 55 islands) and house mouse (30 islands).
- 13. Mice are harder to eradicate than rats: 19% failure rate compared with 5-10% failure rates for attempted eradications of the three rat species. This is probably because mice have a smaller home range, different foraging behaviour and bait densities may have been inadequate. Rats kill mice and mice are actively deterred by rat odour. Rats therefore can suppress mice populations. A number of successful rat eradications have led to subsequent explosions in mice numbers from previously low or undetectable levels.
- 14. The risks to non-target birds and other wildlife from primary and secondary poisoning by the anticoagulant rodenticide Brodifacoum, varies between vertebrate species, being particularly toxic to birds and mammals. However, all vertebrates that eat baits or poisoned prey are at risk. Brodifacoum will persist for at least six months in organs and tissues including the liver, kidney, and pancreas.
- 15. Vertebrate pest control programs in New Zealand using bait containing Brodifacoum have resulted in the primary and secondary poisoning and sub-lethal contamination of non-target species including fourteen indigenous and eight introduced bird species such as the Australasian harrier (Circus approximans), Morepork (Ninox novaeseelandiae), the southern black-backed gull (Larus dominicanus), and kiwi (Apteryx spp.). Populations of three species (Western weka, Stewart Island weka and Pukeko) have been severely reduced in areas where Brodifacoum has been broadcast.
- 16. There are increasing numbers of reports worldwide of wildlife contamination and toxicosis after the use of second-generation anticoagulants such as Brodifacoum. Consequently all

pest control activities require careful risk-benefit assessment in view of their potential to cause adverse environmental impact.

17. The Department notes that significant deaths of non-target birds have occurred, such as the death of 420 birds including between 43 and 46 Bald Eagles, 173 Glaucous-Winged Gulls and Pelagic Seabirds in September 2008 on the 2,800 ha Rat Island in the Aleutians following helicopter and ground-based broadcasting of 46 tonnes of Brodifacoum pellets in seven days. Glaucous-winged gulls nibbled on Brodifacoum pellets and died. Bald Eagles were attracted to the carcasses and succumbed to secondary poisoning. These deaths were not anticipated by the US Fish and Wildlife Service.

, thanks for sending this through promptly. s22

We have no additional changes to make and now accept the proposed conditions.

In regards to Condition 3. We believe the Human toxicologist requirement has been addressed through the Human Health Risk Assessment process led by the NSW Chief Scientist and Engineer at the request of the NSW Minister for the Environment, Local Government and Heritage. Monitoring and reporting back to our Minister with regards to human health will be further addressed as per letter attached

Condition 4 (f) - Twice annual frequency of Woodhen and Currawong survey is correct Condition 4 - Specification of a timeframe for report submission is fine

Thanks

s22

From: s22 **Sent:** Wednesday, 9 August 2017 10:02 AM **To:** s22

Subject: 2016-7703 Approval Proposed conditions post teleconference 8 August [SEC=UNCLASSIFIED] **Importance:** High

Dear s22 and the set of the set o

Thank you for providing comments on the proposed conditions of approval. Following yesterday's teleconference, we have updated the conditions accordingly. In reviewing the agreed changes I have identified a few additional edits I consider necessary to provide clarity regarding the changes. These are summarised below. I have also provided a comment for each in the track change version attached:

- Condition 3 I have reduced the number of TAG members by one to reflect the removal of the human toxicologist.
	- o As discussed, please get back to us with advice regarding how the human toxicologist requirement will be met through other approval/governance mechanisms.
- Condition 4(d) We think specifying the Masked Owl makes clear the intention of this sub-condition.
- Condition 4(f) I had in my notes we discussed a frequency of twice a year. I have amended the condition accordingly. I am seeking your confirmation twice a year is correct, and if so, the amended conditions is implementable.
- Condition 4 (last paragraph) Upon reading the revised sub-condition 4(f), I thought it was appropriate to specify a due date for submission of these results – that way it is clear to you and us when to submit these results (see the above paragraph, where we similarly define a due date (5 months)).

Please reply to s22 and myself as soon as you are comfortable with the revised conditions. Please note - it is the Minister's Delegate who will ultimately decide the conditions which are necessary and convenient for the protection of matters of national environmental significance to attach to the approval.

Feel free to call myself or s22 | if you wish to discuss further.

Regards Assistant Director NSW Assessments North Section Department of the Environment and Energy GPO Box 787 Canberra ACT 2601 **P**(s22 s22 $s22$

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The Hon. Gabrielle Upton MP

Minister for the Environment Minister for Local Government Minister for Heritage

E-MAILED Date $30/6$ By S P

Ref: Min: Doc ID: A545304

Professor Mary O'Kane **Chief Scientist and Engineer GPO Box 5477** SYDNEY NSW 2001

By email: rebecca.radford@chiefscientist.nsw.gov.au

Dear Professor O'Kane May

Thank you for your letter providing me with the Independent Human Health Risk Assessment report for the Lord Howe Island's proposed Rodent Eradication Program, which was reguested by my predecessor and undertaken under your oversight.

The process leading to the assessment has been very thorough and the assessment itself is very comprehensive. I am pleased to accept the report and its recommendations. I intend to act on them by requesting that the Lord Howe Island Board deliver to me a communication strategy, a monitoring strategy and regular reports following the eradication program on community and eradication outcomes.

Thank you for your offer to have your office visit Lord Howe Island to assist with communicating the outcomes of the human health risk assessment. I believe that the Island community will very much benefit from presentation and discussion of the assessment from experts in the field.

At my request, Ms Penny Holloway, Chief Executive Officer of the Lord Howe Island Board is available on (02) 6563 2066 or penny.holloway@lhib.nsw.gov.au should you have any further questions.

Yours sincerely

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Gábrielle Upton MP Minister for the Environment Minister for Local Government Minister for Heritage

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