Supplement to:

Human Health Risk Assessment – Proposed Lord Howe Island Rodent Eradication Program

This supplement revises Section 5.2.2, in part, on page 50 of the subject report.

pellets. This requires a fundamentally different reference value based upon dose levels recognised to produce effects, as opposed to standard no-effect levels.

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

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

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

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

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

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

School Child – (36.5 kg * 0.015 mg/kg) = 0.55 mg

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

5.2.3 Background Exposure

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

Supplement to:

Human Health Risk Assessment – Proposed Lord Howe Island Rodent Eradication Program

This supplement revises Section 7.6, in part, and replaces Table 16 of the subject report.

7.6 Characterisation of Risks from Acute Ingestion of Bait Pellets (continuation)

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, 36.5 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 parameters for the bait pellet characteristics can be used to estimate the number of pellets needed to produce the adverse effect level (**Table 16R**).

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

Child	Dose to Reach Adverse Effect Level (mg)	Number of 10 mm Pestoff 20R pellets*	Number of 5.5 mm Pestoff 20R pellets**
Toddler	0.23	5.6	18.8
School Child	0.55	13.7	45.6

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 18 of the smaller bait pellets. And, the school child would have to ingest more than 13 of the larger bait pellets or more than 45 of the smaller bait pellets. These values have been calculated on the basis of a one-time, daily dose (i.e., the pellets are consumed all at once, or over the course of a day). In light of the relatively slow elimination of brodifacoum, the scenario could be extended to also apply where a child consumed the same number of total pellets over approximately 2 days. Longer scenarios where children consume bait pellets on multiple consecutive days are not anticipated due to the presence of the dye, which would serve to alert adults to the initial incident. This circumstance provides a margin of safety that parents and guardians can consider with regard to exposure incidents. Given the concentration of 20 mg/kg brodifacoum in the bait pellets that would be used for the REP, it would take substantially more than incidental contact or mouthing and ingesting a pellet or two to reach the threshold from WHO. However, rodenticide bait pellets are not intended for consumption and exposure via this scenario should be minimised to the extent possible.

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

For further context to understand the margin of safety between the threshold for adverse effects and the dose of brodifacoum that could be lethal, comparisons can be made to another value. Toxikos (2010) identified 15 mg of brodifacoum as a potentially lethal level for adults. Using the body weights above, this converts to approximately 3.4 mg for a toddler and 8 mg for a school child. For the child receptors, this projected lethal dose is approximately 15 times higher than the threshold for producing readily treatable effects (3.4 mg / 0.23 mg; or 8 mg /0.55 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.