Appendix Q: Detailed Discussions of Controls

Contents

Key points

The Agency proposes that acceptable daily exposure (ADE) and potential daily exposure (PDE) values, tolerable exposure limits (TELs) and workplace exposure standard (WES) values are set for 1080 and substances containing 1080.

Current best practice for possum and rabbit control indicates that an application rate of 30 g 1080/ha is possibly excessive and could be lowered. However, more needs to be known about possible double-sowing before the maximum rate could be lowered.

The current bait colour requirements should be retained.

Changes to the restrictions on methods of use are proposed. These include restricting the application of "Paste containing 1.5 g/kg sodium fluoroacetate" to bait stations and the application of "Soluble concentrate containing 200 g/litre sodium fluoroacetate" when mixed with apple to bait stations.

Further discussion with relevant interested parties is considered appropriate to determine whether controls addressing use of attractants or repellents, bait size and the degree of palatability are necessary.

Q1 Overview

The applicants have provided no analysis as to the suitability of the current suite of HSNO controls (see p 439 of the application) other than to state that risks are currently adequately controlled.

At the time substances containing 1080 were transferred from the Pesticides Act 1979 to the full Hazardous Substances and New Organisms Act 1996 (HSNO Act) framework (1 July 2005), no formal risk assessment was undertaken and as such, the appropriateness of some controls was not fully evaluated. There was no significant public participation in the transfer from the old to the new legislation.

The Agency considers that a review of how some of the controls are working in practice is needed as part of the reassessment process, particularly those which have been recently implemented (permissions under delegation to the Authority), and those which are explicitly available to the Authority but have not previously been evaluated or implemented (eg, regulation 51 of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001).

For clarity, and to address issues raised by submitters regarding inconsistent approaches nationally, the interface between the HSNO Act controls and those under the Resource Management Act 1991 (RMA) and the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act) also warrant examination (refer to Appendix L and section 6 of the Evaluation and Review Report for details of the RMA and ACVM Act requirements).

The Agency notes that under section 77A the Authority has the ability to impose as controls any obligations and restrictions as the Authority thinks fit. Under section 77A(4), the Authority must be satisfied that, against any other specified controls that apply to the substance:

(a) the proposed control is more effective in terms of its effect on the management, use and risks of the substance; or

(b) the proposed control is more cost-effective in terms of its effect on the management, use and risks of the substance; or

(c) the proposed control is more likely to achieve its purpose.

Q2 Discussion of modifications of class 6 toxicity controls

Q2.1 Limiting exposures by setting acceptable daily exposure/reference dose values, potential daily exposure values and tolerable exposure limits (regulations 11–27, Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001)

Q2.1.1 Acceptable daily exposure/reference dose values (regulations 11–21, Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001)

An ADE is an amount of a hazardous substance (mg/kg body weight/day) that, given a lifetime of daily exposure, would be unlikely to result in adverse health effects. A reference dose (RfD) is a similar measure that can be used to protect against a specific toxic effect of concern. Regulation 11(1) of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 determines when an ADE/RfD is required to be set:

(1) This regulation applies to a class 6 substance if—

(a) it is likely to be present in—

(i) 1 or more environmental media; or

(ii) food; or

(iii) other matter that might be ingested; AND

(b) it is a substance to which a person is likely to be exposed on 1 or more occasions during the lifetime of the person; AND

(c) exposure to the substance is likely to result in an appreciable toxic effect.

If all three of the requirements of this regulation are met then an ADE value or one or more RfD values must be set for a substance (or for one or more components of the substance) by the Authority and these values must be derived from an assessment of the toxicological data available for the substance (or for its components) in accordance with regulations 12 to 21.

On a review of the relevant toxicology data, the Agency considers that an **ADE = 0.02 µg/kg bw/day** should be adopted for 1080, as discussed in section M2.2.2 of Appendix M.

Q2.1.2 Potential daily exposure values (regulations 22–23, Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001)

If an ADE is set for a substance, a PDE value for each exposure route must also be set. Potential daily exposure is an amount of substance (mg/kg body weight/day) that is calculated in accordance with regulation 23 for a particular exposure route.

The PDE is integral for the calculation of a TEL.

The standard approach for determining PDE values would be to apply the following standard factors to the ADE for each exposure route: food (70%), drinking water (20%), inhalation (10%), dermal (10%) and other (10%). In the case of 1080 these values were not considered appropriate. The values proposed in Appendix M were food (30%), drinking water (50%) inhalation (10%) and dermal (10%).

Therefore, the Agency proposes that the following PDE values are set for 1080 and substances containing 1080:

PDE_{FOOD} = 0.006 µg/kg bw/day

$PDE_{DRINKING\ WATER}$ = 0.010 µg/kg bw/day

$PDE_{INHALATION}$ = 0.002 µg/kg bw/day and

PDE_{DERMAL} = 0.002 µg/kg bw/day should be set for 1080.

Q2.1.3 Tolerable exposure limits (regulations 24–27, Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001)

Tolerable exposure limits are designed to limit the extent to which the public is exposed to hazardous (toxic) substances. A TEL represents the maximum concentration of a substance legally allowable in a particular

medium, and can be set as either a guideline value or an action level that should not be exceeded. For the purposes of setting TELs, an environmental medium is defined as air, water, soil or a surface that a hazardous substance may be deposited onto.

TELs are established from PDE values, which are established from ADE values.

A TEL_{water} would be appropriate to ensure that emissions to surface water from a factory, store areas, aircraft loading operation and from 1080 application are not excessive. Such a value could also be relevant in the event of a transport incident (accident/spillage).

The Hazardous Substances (Sodium Fluoroacetate) Transfer Notice 2005 (17 June 2005) established a TEL_{water} of 3.5 µg/litre. This was based on the PMAV established by the Ministry of Health, rather than on the derivation of an ADE and PDE_{water}. The Agency proposes that this value is retained pending revision of the PMAV by the Ministry of Health (see Appendix M).

Q2.1.4 Permissible maximum exposure and TEL_{water}

The Agency notes that there may be potential confusion between the TEL_{water} and the Ministry of Health's PMAV. The PMAV is discussed in Appendix M, and this includes the observation that the Ministry of Health proposes a review of the value.

This confusion has been enhanced by the adoption of the PMAV as the TEL_{water} in the Gazette Notice, also by the use of the drinking water exposure assumptions when deriving the TEL_{water} above. Nevertheless, this approach is taken because:

- A member of the public (hunter, tramper etc) could use a stream for their sole source of drinking water when in the bush and the assumption is that they would consume 2 litres per day.
- The absorption of 1080 from skin contact with contaminated stream water is considered to be lower than from ingestion, so in this instance the oral route was used.

The Agency makes the following comments on the differing purposes for the two values. The Agency notes that often the PMAV has been used when a TEL_{water} would really have been the more relevant standard for surface water.

The PMAV should really be used to assess a 1080 concentration found in water, either at the:

- point of use at the tap (whether reticulated or private supply, including roof water), or
- output from a reticulated (public) water supply.

If the concentration level of a surface or ground water sample is to be assessed, it would be appropriate to compare this with the TEL_{water} proposed above.

Q2.2 Workplace exposure standards

Workplace exposure standards are designed to protect persons in the workplace from the adverse effects of toxic substances. A WES is an airborne concentration of a substance (expressed as mg substance/m^3 of air or ppm in air), which must not be exceeded in a workplace and only applies to places of work to which the public does not have access (regulation 29(2) of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001).

Regulation 29(1) of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 determines when a WES is required to be set. If all three of the requirements of this regulation are met then a WES is set.

Regulation 29 states:

(1) This regulation and regulation 30 apply to a class 6 substance if,—

(a) under the temperature and pressure the substance is to be used in, it can become airborne and disperse in air in the form of inspirable or respirable dust, mists, fumes, gases or vapours; and

(b) human exposure to the substance is primarily through the inhalation or dermal exposure routes; and

(c) the toxicological and industrial hygiene data available for the substance is sufficient to enable a standard to be set.

When setting WESs, the Authority must either adopt a value already proposed by the Department of Labour or already set under HSNO, or adopt a value set in another jurisdiction or derive a value by taking into account the matters described in regulation 30(2) of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations.

The Agency notes that a Department of Labour WES value has been set for 1080. The Agency considers this value should be applied to the technical grade active and all the 1080 formulated products, although the Agency notes that the likelihood of airborne emissions from some of the formulations are remote.

The Department of Labour WES value is as follows:

Sodium fluoroacetate (1080) (skin, bio) [CAS number 62-74-8]

0.05 mg/m^3 (DoL 2002a)

As discussed and referred to extensively in Appendix M, the Department of Labour also established a Biological Exposure Index (BEI). This is not discussed further here as there is no provision for establishing such values under the HSNO legislation.

It is further noted that the conditions of regulation 29(1)(c) are not met as there is insufficient industrial hygiene data available to enable a WES to be set for any other of the constituent components.

Q2.2.1 Documentation requirements (control code I21) and secondary identifiers for toxic substances (control code i16) and corrosive substances (control code I10)

Regulation 39(5) of the Hazardous Substances (Identification) Regulations 2001 states that certain corrosive and toxic components are required to be specified on documentation. Regulations 25(e), 25(f) and 19(f) state that certain corrosive and toxic components are required to be specified on the label. In March 2006, the Hazardous Substances Standing Committee determined the concentrations triggering a need for labelling and documentation.

Regulation 39(5) states:

> The requirements of regulation 19(f) or (as the case requires) regulation 25(e) apply to all documentation; but any ingredient required by that provision to be identified (other than an ingredient to which regulation 26 applies) must also be identified by any Chemical Abstract Services number allocated to it.

Regulation 25(e) states:

> a toxic substance must be identified by …
>
> information identifying, by its common or chemical name, every ingredient, that would, independently of any other ingredient, give the substance a hazard classification of 6.1A, 6.1B, 6.1C, 6.5, 6.6, 6.7, 6.8, or 6.9, and the concentration of that ingredient in the substance.

Regulation 25(f) states:

> a toxic substance must be identified by …
>
> information identifying every ingredient (other than an ingredient referred to in paragraph (e)) that would, independently of any other ingredient, give the substance a hazard classification of 6.1D, and the concentration of the ingredient that would contribute the most to that classification.

Regulation 19(f) states:

> a corrosive substance must be identified by …
>
> If the substance contains any ingredient in such a concentration that the ingredient would, independently of any other ingredient,

cause the substance to be classified as class 8.2 or class 8.3, in respect of each such ingredient,—

(i) its common or chemical name; and

(ii) a statement of its concentration in the substance.

Under these regulations, as determined by the HSSC (March 2006), the following components need to be specified on the label and documentation:

The only triggering component with respect to class 6 classification is the 1080 (taking into account a single change proposed to one substance that is a formulation of 1080 (see Appendix B)). The identification of 1080 is required on the label and documentation for 1080 and all substances containing 1080.

Q3 Discussion of modifications of class 9 ecotoxicity controls

Q3.1 Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001

Q3.1.1 Regulations 32–47 environmental exposure limits (control E1)

The Hazardous Substances and New Organisms (Approvals and Enforcement) Act 2005 has added a new section 77B to the HSNO Act, providing the Authority, amongst other matters, with the ability to set environmental exposure limits (EELs) as guideline values, rather than the previous pass/fail values. However, until the Agency has developed formal policy on the implementation of section 77B, this avenue is not available.

The Agency proposes that no EELs are set for 1080 or substances containing 1080 at this time, including deletion of the default values. Once the section 77B policy has been developed, a review of this position may be required.

Q3.1.2 Regulation 48 application rate for a substance within an application area (control E2)

The application rate for aerially applied 1080 is 30 g 1080/ha (Schedule 5, Hazardous Substances (Sodium Fluoroacetate) Transfer Notice 2005 (*New Zealand Gazette* Issue No 92, 17 June 2005) (as amended)). In 2002, before the transfer of substances containing 1080, consultation with the vertebrate pest control operators indicated that a rate of 30 g/ha would allow flexibility to address specific pest problems which may arise, for example, introduction of a new pest (as in a biosecurity emergency) or where a particularly high pest density required a high application rate (ERMA New Zealand 2002).

Current best practice for possum and rabbit control indicates that 30 g 1080/ha is possibly excessive and could be lowered, with present

rates for possums at 2.4–7.5 g 1080/ha and for rabbits 2–8 g 1080/ha (Additional information supplied by applicants 22 December 2006). However, more needs to be known about possible double-sowing before the maximum rate could be lowered.

The Agency notes that use of substances containing 1080 in a biosecurity emergency can now be managed under section 49D of the Act (application for approval for use to use agricultural compound or medicine in special emergency), a provision that was not available at the time of transfer of substances containing 1080.

The Agency notes that the applicant claims that the current application rate is currently managing risks to non-target species (see Section 4.1A of the application – environmental effects register). The Agency notes, however, that the rate is only applicable to aerial application and is not set on the basis of any risk assessment.

Q3.1.3 Regulation 51 use of ecotoxic substances as bait (control E3)

Regulation 51 (use of ecotoxic substances as bait (Class 6, 8 and 9 Controls Regulations)) explicitly provides for the Authority to specify one or more of:

- colour
- methods of release
- repellents or attractants to be used with the substance
- bait size
- degree of palatability.

Of the above matters, only bait colour and method of release were specified (Schedule 6; Hazardous Substances (Sodium Fluoroacetate) Transfer Notice 2005 (*New Zealand Gazette* Issue No 92, 17 June 2005) (as amended)) when substances containing 1080 were transferred from the Pesticides Act 1979 to the HSNO Act 1999.

Bait colour

Schedule 6 of Hazardous Substances (Sodium Fluoroacetate) Transfer Notice 2005 (*New Zealand Gazette* Issue No 92, 17 June 2005) (as amended) requires that all substances laid as bait are dyed either blue or green. The requirement that baits are dyed green originated under the Pesticides Act 1979 and Pesticides (Vertebrate Pest Control) Regulations 1983, that is, regulation 23 specified the colour of baits.

> Colour of bait
>
> (1) No person shall prepare, apply, or otherwise use a bait containing a controlled pesticide specified in Part 1 or Part 2 of Schedule 1 to the Act except a bait that is dyed green within the range of 221 to 267 as described in the New Zealand Standard

> Specification 7702:1983 declared under section 23 of the Standards Act 1965."

The rationale for requiring that baits are dyed green was based on the effectiveness of the colour in reducing the visual attractiveness to birds (eg, Kalmbach and Welsh 1946; Caithness and Williams 1971).

During consultation with industry prior to the transfer of vertebrate toxic agents to the full HSNO Act, it was apparent that there had been problems formulating baits to the specific shade of green specified, and that more recent research with New Zealand native birds indicated that blue may also be an effective visual deterrent for North Island robins, *Petroica australis* and weka, *Gallirallus australis* (Hartley et al 1999, 2000). Brown was the least preferred colour for both species. Yellow and green coloured test samples were pecked at more frequently by robins compared with red, blue or brown (Hartley et al 1999). It was noted that after the first day, weka rapidly increased consumption of all coloured foods and further investigations of a more active deterrent may be required for these birds (Hartley et al 2000). Possums are not deterred by either blue or green dyed cereal baits (Day and Matthews 1999).

At present, any pre-fed, non-toxic bait is not dyed so that people handling the bait can readily differentiate between toxic and non-toxic pellets (Brown and Urlich 2005). However, in the Haungaroa operation, two pre-feed drops occurred, with the second using bait which was non-toxic but also dyed green rather than the usual undyed bait used in the first pre-feed (Epro 2005). The Agency assumes that this non-toxic bait was dyed due to potential concerns regarding taste/bait aversion. The Agency considers that where dyeing of non-toxic pre-feed is carried out, operators should take into consideration fully communicating this aspect of the operation with the local community.

Brodifacoum baits are dyed blue to make them distinguishable from 1080 baits (Graeme Butcher, personal communication, cited by Brown and Urlich, 2005).

See also the section on bird repellents below.

Methods of release

Aerial application versus ground application

Pellets containing 0.4–0.8 g/kg sodium fluoroacetate, pellets containing 1.5–2.0 g/kg sodium fluoroacetate and Soluble concentrate containing 200 g/litre sodium fluoroacetate (when mixed with food bait) are the only substances containing 1080 that are currently permitted for aerial application, all other substances containing 1080 must be applied by ground based methods.

Ground application

The Agency notes that ground based application methods cover contained (eg, bait station and bait bag application) and uncontained application (eg, application to natural features).

The Agency notes that the substance "Paste containing 1.5 g/kg sodium fluoroacetate" covers both an apple pulp paste and a peanut based paste. The approval for both these substances (HSNO approval number HSR002421) permits contained and uncontained ground based application methods for these substances.

Studies indicate that weka, robin and pukeko are likely to consume the apple pulp based paste where they can gain access to it (ie, following uncontained application) (refer to Appendix F). The Agency considers that a control requiring use of these pastes in bait stations where weka, robin and pukeko are present would be appropriate to mitigate risks posed to these species. Consideration of the impact of this management action on the control of rabbits will also be required.

The applicants advise that the peanut based paste is used only in bait stations and state that the product label specifies application of the paste in weatherproof pots, in bait stations or in appropriately marked biodegradable bags (additional correspondence from applicants, 13 February 2007). Additionally the applicants advise that testing of consumption of this paste by non-target species has not been carried out due to its contained application. The Agency considers that as there is insufficient information to assess the risks to non-target species associated with this paste it would be appropriate to limit its use to contained applications in weatherproof pots, in bait stations or in appropriately marked biodegradable bags.

The Agency has identified in Appendix N that the attractiveness of prepared non-toxic apple baits to native birds of has been evaluated in cage trials by Thomas et al (2003). The Agency notes that conclusion of this study in which the authors recommend that apple bait should only be used in bait stations. The Agency considers that this recommendation should be applied to "Soluble concentrate containing 200 g/litre sodium fluoroacetate" when mixed with apple to form bait.

Repellents and attractants (lures)

For a repellent to be effective it needs to both deter contact/consumption by the non-target species for which protection is sought and not adversely affect the palatability of the bait to the target species. Likewise, lures to attract target species to the bait need to be unattractive to non-target species.

Invertebrate repellents

Incorporation of an invertebrate repellent into baits containing 1080 would reduce the potential risk to both invertebrates which may feed on the baits, and to consumers of the invertebrates (Spurr 1999). The Agency notes that diethyl toluamide or DEET, dimethyl phthalate, citronella oil, eucalyptus oil, neem oil and alpha-cypermethrin were identified by Spurr and McGregor (2003) as being worth further investigation as antifeedants with the key initial investigative need being an assessment of palatability to possums and rodents, the results of these trials are detailed in Appendix F.

Repellence of 0.15% cinnamon oil did not affect the number of cave weta or cockroaches observed feeding on baits, in contrast with the field results of Sherley et al 1999 which indicated that significantly lower numbers of invertebrates were observed on baits containing cinnamon oil. The difference may be due to the wider diversity of invertebrates in the field compared to that of the caged trials.

The applicants advise that they are not aware of any on-going research on invertebrate repellents/antifeedants (G Sherley, personal communication, 28 February 2007).

In conclusion, that Agency considers that if a suitable invertebrate repellent were identified at some point in the future, the extra costs of adding the substance to bait would need to be balanced against the benefits of doing so.

Bird repellents

The applicants supplied a couple of studies detailing testing of bird repellents. These studies are detailed in Appendix F. The Agency considers that further trials with the bird repellent may be warranted given the lack of replication and issues with monitoring possum indices noted in the trial on carrot. The less-than-target toxic loading on the carrot may also have had a role in the lower than expected residual trap catch index, but is speculation only.

The effectiveness of 0.1% cinnamon oil, which is incorporated into formulations as a lure for possums, as a bird repellent has been investigated by Spurr (1993). Spurr (1993) determined that cinnamon in carrot and cereal baits deterred kaka, kokako and Antipodes Island parakeet for the first day only.

Deer repellent

The Agency notes that a deer repellent is available and in use on carrot bait (eg, repellent has been used at Hatepe in the Kaimanawa Forest Park (Speedy 2003), in the Tataraakina area in northern Hawkes Bay (Nugent et al 2004) and in the Hauhangaroa Ranges (Epro 2005)).

The Agency has identified a number of studies addressing the use of deer repellent (see Appendix F). The Agency considers that, given the complexity of the issues, and the very site-specific nature of deer management, it is not appropriate that a control is added to any substances containing 1080 that would require the use of a deer repellent.

Attractants (lures)

Use of inappropriate lures to attract target species to bait may result in potentially significant adverse effects on non-target species. Use of raspberry lure in the 1970s was reported to have resulted in numerous deaths of birds and was subsequently 'banned' (Harrison 1978).

Cinnamon oil is used to mask the odour and taste of 1080 to possums (Morgan 1990). Other lures noted as being routinely used in significant quantities include spearmint and cloves (additional information from applicants, 22 December 2006). See above sections for further discussion regarding repellence of cinnamon to invertebrates and birds. The Agency has identified a range of studies detailing testing involving lures and non-target species (for example birds and bats). The details of these studies are detailed in Appendix F.

Bait size and bait quality

The Agency has incomplete information in these areas. However, the Agency considers that there is a need to ensure that at all stages of the lifecycle bait are being handled in a way that minimizes fragmentation. The Agency specifically notes Landcare Research Report LC9596/52 for Canterbury Regional Council that indicates significant differences in bait size distribution from the different cutting machines. Additionally, the Agency notes Brown and Urlich (2005) specify that a review of sowing bucket design and spread quality is in progress by DoC Southland. The Agency considers that issues surrounding bait size and bait quality is an area where discussion with relevant industry would be advantageous, possibly with a view to developing an industry wide code of practice for the preparation of bait materials (carrot, apple, oats) from the soluble concentrate containing 1080 to provide greater consistency amongst users.

Palatability

Non-target species

The Agency notes that the current approvals for substances containing 1080 cover a variety of potential formulations and allow for the substitution of excipient ingredients (eg, for the purpose of decreasing the palatability of the bait to non-target species). Provided that the overall hazard classification of the substance is not varied by the formulation change, ERMA New Zealand approval for the new formulation would not be required. The Agency considers, however, that in some instances such a formulation change may result in a change in risk profile that would be of interest from the purpose of ensuring that risks are managed.

The issue of palatability for non-target species needs to be considered at the approval stage for modifications to existing formulations and/or development of new substances containing 1080. It might be prudent to require testing for palatability to non-target species, even when there is no apparent change in hazard classification, since the change in bait matrix/lure/repellent may increase the risks to non-target species during use (Morgan et al 1997 – re change in sugars)

Additionally, the Agency notes that there are issues related to palatability of baits to target species. The effects of field weathering of RS5 and Wanganui No 7 baits on palatability to possums was assessed in two different New Zealand locations, Mackenzie Basin and Westland, in summer and winter (Thomas et al 2004). Overall, palatability declined more rapidly in Westland in winter (cold, wet) compared with Mackenzie Basin in summer (warmer, drier).

Cage trials showed that possums with a choice between fresh RS5 bait and field weathered (up to two months old) still ate bait with visible mould and smelling fermented. Bait remained palatable for the three weeks of the trial (Thomas et al 2004). In another study, 94% of possums found and ate baits in the first week after application (Morgan 1982), suggesting that leaching from baits may have a greater effect on sub-optimal kill rates than loss of palatability.

The Agency notes that this is a general issue that is applicable to all vertebrate toxic agents, not just substances containing 1080, the Agency considers that discussion with industry is required to develop a process for ensuring such changes in risk profile are appropriately assessed.