Ministry for Primary Industries
Manatū Ahu Matua

Operation Concord – Required actions for implementing Engagement Plan

Drafted: 7 Jan 2015

Advising potentially affected infant formula manufacturers is considered an important next step in supporting an adequate response to the Concord threat because:

1. Increased security of the supply chain and protection of consumer safety – i.e. manufacturers may need to increase security, general vigilance and implement milk and/or product testing.
2. Careful management of public communications [redacted] Manufacturers have a shared interest with government in maintaining confidence in the safety and supply of threatened products. To minimise the risk of confusing information being provided to consumers it is important that manufacturers are informed. 9(2)(c)
3. Improved validation of the supply chain [redacted] 6(c)

Validated methods for detecting 1080 in raw milk and infant formula are expected to be available [redacted] 9(2)(g)(i)

[redacted] 6(c), 9(2)(d), 9(2)(g)(i)

Expected completion dates and rationale for the following prerequisite actions must be in place before this can occur:

Pre-requisite action	MPI Responsibility*	Status	Deadline for completion	Rationale
1. A validated testing method for detecting 1080 in raw milk and infant formula		Underway		
2. Appreciation of capacity in New Zealand to test large volumes of raw milk and infant formula samples		Completed		
3. MPI has strategy to manage testing priorities until testing capacity is sufficient to accommodate all testing requests		Completed		
4. A testing plan to prioritise the milk and milk products to test		Completed		
5. Confirm an agreed contingency plan should 1080 contamination be detected in ingredients or products.		Underway		

9(2)(d)

6. Comms Strategy and material to proactively inform media	Completed		To manage release of information
7. Agreed procedure for reaching out to other manufacturers	Completed subject to Watch Group and ODESC consideration	7 Jan 2015	To mitigate risk of uncontrolled release of information and potential concerns of contacted manufacturers
8. [redacted]			
9. [redacted]			
10. Communication strategy and associated messaging for stakeholders and/or media	Completed but ongoing. Subject to revision as circumstances dictate		
11. Communications plan for responding to test results confirming 1080 deliberate contamination once 1080 testing regime is in place	Underway	16 Jan 2015	To mitigate any concerns from domestic and foreign customers, public and foreign regulators. To initiate agreed action plan for mitigating risk of contaminated product (trigger recall etc)

9(2)(a)

6(a)

Covering email to manufacturers]

Thank you for taking time to speak to me.

MPI is aware of a potential issue that could affect the dairy industry and which we believe could have an impact on your business.

Because of the sensitive nature of the issue, I am unable to provide you further details over and above those that I gave you on the phone, but am inviting you or a representative of your company to a meeting with a number of different manufacturers.

We propose to hold a meeting at the offices of the Ministry of Primary Industries, 25 The Terrace, Wellington on Tuesday 10th February commencing at 10am and it expected to finish by 2.30pm.

I am inviting you or your nominated representative to attend the meeting, but wish to reiterate that only one representative from your organisation will be allowed access, and if more turn up they will be refused entry. In order to facilitate the meeting I should be grateful if you could notify us by email at: ocliaison@mpi.govt.nz of who your nominated attendee will be together with contact telephone and email details.

During the meeting you will be briefed on the situation and given some written documentation for you to consider. You will be given time to listen to the presentations, read the documentation and to ask questions. You will be informed of the proposed actions going forward, and opportunities to discuss the issue and raise further questions. We are also proposing to hold further events to assist your business in relation to the issue and more details will be provided at the meeting.

Because of the confidential nature of this issue I attach a confidentiality agreement for the nominated attendee to sign and return to the above email address or bring with them on the day. There will be blank forms available at the meeting reception should they forget them. Should your representative be unwilling to sign the confidentiality agreement, they will be refused entry to the meeting.

In fairness to all businesses attending you will not be permitted to take mobile or electronic devices into the meeting and these will be left with MPI officials for the duration of the meeting.

I look forward to seeing you at the meeting. Because of the confidential nature of the issue to be discussed I cannot enter into any further discussion around this before the meeting, however if you wish to discuss any arrangements relating to the meeting to itself please feel free to email [redacted] the Operations Manager at ocliaison@mpi.govt.nz 9(2)(a)

Covering email to global suppliers

Thank you for taking time to speak to me.

9(2)(d) [redacted], MPI is aware of a potential issue that could affect the dairy industry and which we believe could have an impact on your business.

Because of the sensitive nature of the issue, I am unable to provide you further details over and above those that I gave you on the phone, but am inviting you or a representative of your company to a meeting with a number of other infant formula global suppliers.

We propose to hold a meeting at the offices of the Ministry of Primary Industries, 25 The Terrace, Wellington on Wednesday 11th February commencing at 11am and it expected to finish by 3pm.

I am inviting you or a nominated representative to attend the meeting, but would point out that only one or two representatives from your organisation will be allowed access. In order to facilitate the meeting I should be grateful if you could notify who the nominated attendee from your business will be together with their contact telephone and email details by email to: ocliaison@mpi.govt.nz

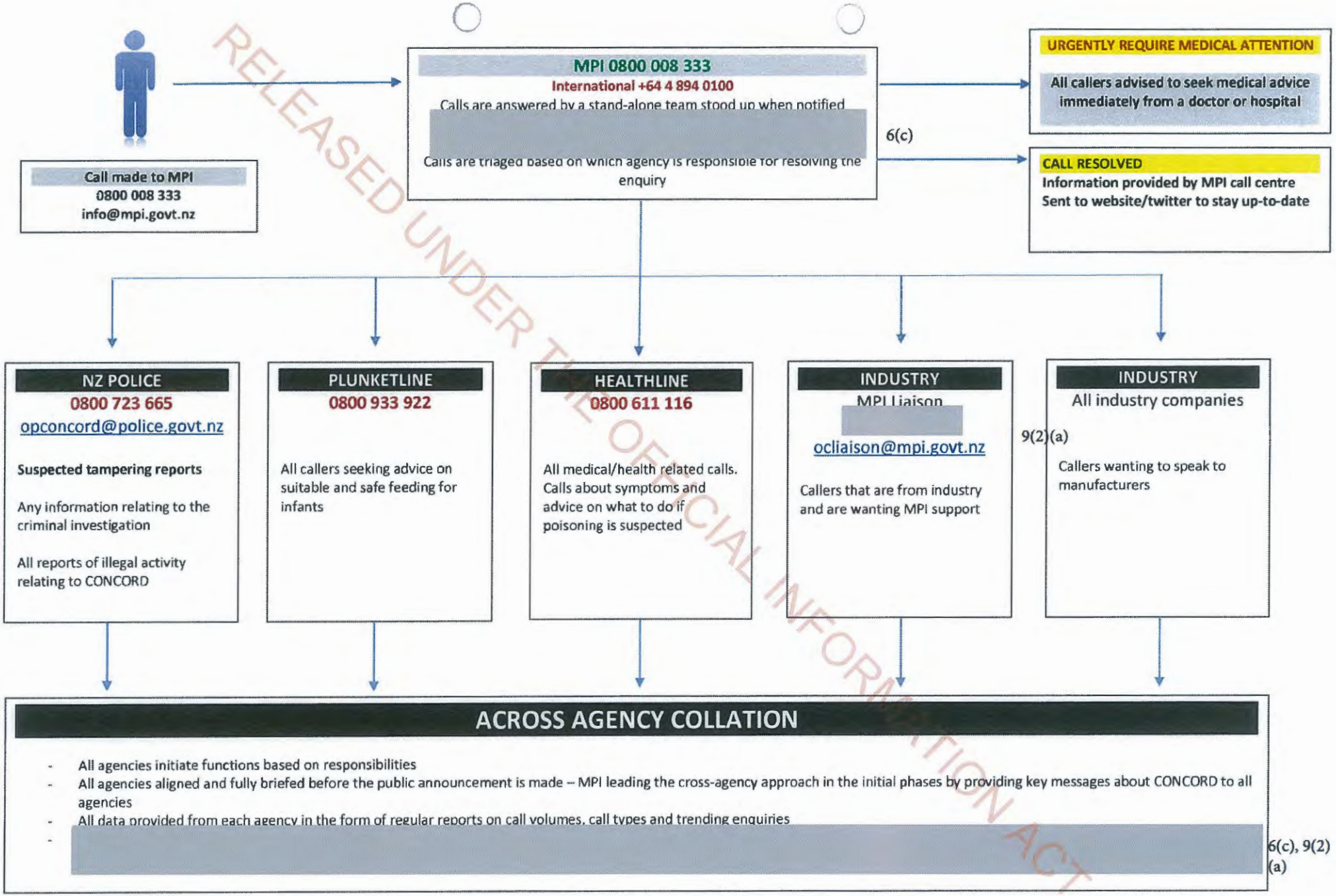
During the meeting you will be briefed on the situation and given some written documentation for you to consider. You will be given time to listen to the presentations, read the documentation and to ask questions. You will also be informed of the proposed actions going forward. We are inviting you to attend the meeting, as we will be briefing several of your manufacturing customers just prior to this meeting and would prefer that you hear about the issue directly from us rather than hearing about the issue second hand from them.

Because of the confidential nature of this issue I attach a confidentiality agreement which I should be grateful if the nominated attendee(s) could sign and return to the above email address or bring it with them on the day. There will be blank forms available at the meeting reception should they forget them. Should your representative be unwilling to sign the confidentiality agreement, they will be refused entry to the meeting.

In fairness to all businesses attending you will not be permitted to take mobile or electronic devices into the meeting and these will be left with MPI officials for the duration of the meeting.

I look forward to seeing you at the meeting. Because of the confidential nature of the issue to be discussed I cannot enter into any further discussion around this before the meeting, however if you wish to discuss any arrangements relating to the meeting to itself please feel free to email [redacted] at ocliaison@mpi.govt.nz 9(2)(a)

[redacted] |Response Manager
Readiness and Response Directorate | Investigation, Readiness and Response Group
[redacted] | Pastoral House 25 The Terrace | PO Box 2526 | Wellington | New Zealand 9(2)(a)
[redacted]



MINISTRY OF HEALTH
MANATŪ HAUORA

New Zealand Government

Suspected 1080 (Fluoroacetate) Ingestion from Contaminated Infant or other Formula

Guidance for general practitioners and urgent care medical specialists

17 March 2015

Infant & child feeding

Key points for parents

- Infants under one year of age should be breastfed, or fed with a properly prepared, commercial dairy or soy based infant formula.
- Mothers who have stopped breastfeeding recently may be able to restart breastfeeding again with help from their midwife, lactation consultant, general practitioner or Well Child nurse.
- Exclusively breastfed infants are **not** at risk of formula contamination.
- The Ministry of Health does **not** recommend that parents feed infants **under one year of age** pasteurised whole or homogenised cow's milk, or prepare home-made alternatives to infant formula.
- If your baby is on a special formula because of food allergy or special dietary requirements, do **not** change your formula without consulting with a dietitian, paediatrician or your general practitioner.
- You should follow Ministry for Primary Industries (MPI) advice on how to ensure formula is free from contamination or tampering. Their advice to consumers is that if any food product appears to have been tampered with – for example, seals broken or punctured – then it should not be consumed and it should be reported to the Police on 0800 723 665. This guidance may be downloaded from the following website: www.foodprotection.govt.nz/for-consumers/ways-to-check-for-tampering

Keeping your baby or child and yourself safe

- You may wish to provide the parents with the *Feeding your baby infant formula* information sheet compiled by the Ministry of Health and Ministry for Primary Industries.
- The ability for anybody to deliberately contaminate infant and other formula during manufacturing is very low. There is no evidence this has occurred.
- New Zealand formula is safe to consume at the time of manufacture and distribution – either for retail in New Zealand or export.
- The Ministry for Primary Industries (MPI) have put a new 1080 testing regime in place that gives the Government a high degree of confidence that the products covered by the threat do not contain traces of 1080.

- To further protect the products, infant formula and other formula products are usually sold in tamper-evident packaging, which is designed to help you see if someone has opened or interfered with the packaging.
- Parents should follow Ministry for Primary Industries (MPI) advice on how to ensure formula is free from contamination or tampering. Their advice to consumers is that if any food product appears to have been tampered with – for example, seals broken or punctured – then it should not be consumed and it should be reported to the Ministry for Primary Industries on 0800 008 333 or info@nzfoodinfo.govt.nz. This guidance will be downloaded from the following website: www.foodprotection.govt.nz/for-consumers/ways-to-check-for-tampering

1080 (fluoroacetate)

- Fluoroacetate is a pesticide used on targeted pests in New Zealand.
- It is **highly toxic** to humans.
- Fluoroacetate is a white, tasteless and odourless fine powder that can look like icing sugar or fine salt. Diluted solutions may taste like vinegar.
- Fluoroacetate is readily absorbed and acts rapidly to disturb the citric acid (Krebs) cycle. The poison competitively inhibits enzyme activity and oxidative metabolism, leading to accumulation of citrate and lactate, resulting in a metabolic acidosis and electrolyte abnormalities (hypocalcaemia and hypo- or hyperkalaemia).
- Metabolically active tissues, such as cardiac, renal or neural tissue, are critically affected, leading to multi-organ failure, while biochemical imbalances lead to further morbidity.

Presentation of symptoms

- The poison acts rapidly. Depending on the dose ingested, symptoms usually occur **within 30 minutes of exposure and progress rapidly. Lower doses may take longer (up to three hours) to produce symptoms.**
- A full case definition is available to download from www.health.govt.nz/our-work/environmental-health/contamination-infant-and-other-formula-products/definition-fluoroacetate-1080-poisoning

Infants or children

- Symptoms of ingestion are that of an **unwell** infant or child, and are initially non-specific. Clinicians evaluating a sick child should follow normal assessment and management approaches.
- If the infant or child is **asymptomatic at presentation or four hours after last feed**, and you are confident the child will be adequately observed, it is reasonable to discharge the child home. Please provide the pareuts with iuformation about recognition of illness. This information is available in the back section and back cover of the *Well Child Tamariki Ora – My Health Book* (Danger Signs – Baby and Child Sickness) and can be downloaded from the following website: https://www.healthed.govt.nz/resource/well-child-tamariki-ora-my-health-book
- If a child is mildly unwell, has been symptomatic for several hours but is NOT becoming progressively worse, it is extremely unlikely that this illness is due to fluoroacetate poisoning. Other diagnoses need to be considered, investigated and managed accordingly.

- The early and late signs of fluoroacetate poisoning are shown below.

Early signs	Irritable or inconsolable
	Rapid shallow breathing
	Abdominal pain
	Vomiting
Late signs	Collapse or unresponsiveness
	Seizures

- The child may also be flushed in the cheeks, sweaty, or appear pale and apprehensive, or have glazed eyes and not focusing on anything.

Adults

- Symptoms of ingestion are that of an **unwell** adult, and are initially non-specific. Clinicians evaluating an unwell adult should follow standard assessment and management clinical pathways.
- If the patient is **asymptomatic at presentation or four hours after consumption of the formula**, and you are confident the patient will be adequately observed, it is reasonable to discharge for 24-hour home observation. It is important the key home care carer/observer is fully briefed about warning symptoms and signs indicating 1080 poisoning and should have a low threshold for seeking ED review on suspicion.
- If an adult is mildly unwell, has been symptomatic for several hours but is **not** becoming progressively worse, it is extremely unlikely that this illness is due to fluoroacetate poisoning. Other diagnoses need to be considered in the differential diagnosis. The decision to pursue 1080 testing is subject to the judgement of the treating clinician.
- The early and late signs of fluoroacetate poisoning are shown below.

Early signs	Apprehension and agitation
	Rapid shallow breathing
	Abdominal pain
	Vomiting
Late signs	Confusion and decreasing level of consciousness
	Coma
	Seizures

- Adult patients may also be flushed in the cheeks, sweaty, appear pale, apprehensive, and may appear glazed or unresponsive.

Initial management of suspected fluoroacetate poisoning

- There is no antidote for fluoroacetate poisoning.
- If you are concerned that the patient is seriously unwell, call '111' Emergency Services immediately
- Management of suspected poisoning is supportive and requires hospital level care. Prompt referral and transfer is paramount as other potential causes of presentation need to be investigated.
- Do not induce vomiting. As fluoroacetate is readily absorbed into the body after ingestion, inducing vomiting will not help to decrease toxicity and in fact may cause more harm due to aspiration or choking.
- Benefits from activated charcoal are not proven and it is NOT recommended that this be used outside of a hospital setting due to risk of aspiration.
- Clinicians are reminded that section 74 of the Health Act 1956 requires medical practitioners to notify medical officers of health of cases of listed notifiable diseases, in particular acute gastroenteritis and poisoning arising from chemical contamination of the environment. A notification requirement is also mandated under section 143 of the Hazardous Substances and New Organisms Act 1996 requiring hospitals and medical practitioners to notify hazardous substances injuries to medical officers of health.
- Medical practitioners are asked to urgently notify their medical officer of health of possible, probable or confirmed cases of fluoroacetate (1080) poisoning by phone, fax, email or via the Hazardous Substances Disease and Injury Reporting Tool (HSDIRT) included in best practice decision support (BPAC), My Practice and Profile for Windows patient management systems (https://www.bestpractice.org.nz).
- Medical officers of health are then asked to urgently inform the Ministry of Health of suspected or confirmed cases.

Infants or children

- If possible, please ask the family to keep the suspect infant formula in a safe place, away from further human or animal contact, so further testing can be done if needed.
- If parents bring the suspect formula with them, please handle it as little as possible, place in a clean cardboard box, store it securely and label it with the child's admission label. The police may request the formula for forensic examination.
- You may wish to provide the *Feeding your baby infant formula* information sheet compiled by the Ministry of Health and Ministry for Primary Industries. This will be available to download from the website: www.foodprotection.govt.nz/for-consumers
- Please ask the family to bring the child back to the emergency department for assessment if the child has any of the symptoms stated on the back cover of the Well Child Book. If transport issues are present or the child becomes more unwell, advise them that a '111' Emergency Services call should be made.

Adults

- If possible, please ask the individual or others to keep the suspect formula in a safe place, away from further human or animal contact, so further testing can be done if needed.
- If individuals bring the suspect formula with them, please handle it as little as possible, place in a clean cardboard box, store it securely and label it with the patient's admission label. The police may request the formula for forensic examination.

HP6154

MINISTRY OF HEALTH
MANATŪ HAUORA

New Zealand Government

Suspected 1080 (Fluoroacetate) Ingestion from Contaminated Infant Formula or other Formula

Guidance for midwives, Well Child/Tamariki Ora nurses and dietitians

17 March 2015

Infant & child feeding

Key points for parents to keep infants and children safe

- Infants under one year of age should be breastfed, or fed with a properly prepared, commercial dairy or soy based infant formula.
- Mothers who have stopped breastfeeding recently may be able to restart breastfeeding again with help from their midwife, lactation consultant, general practitioner or Well Child nurse.
- **Exclusively breastfed infants are NOT at risk** of formula contamination.
- The Ministry of Health does **not** recommend that parents feed infants **under one year of age** pasteurised whole or homogenised cow's milk, or prepare home-made alternatives to infant formula.
- If your baby is on a special formula because of food allergy or special dietary requirements, do **not** change your formula without consulting with a dietitian, paediatrician or general practitioner.
- You should follow Ministry for Primary Industries (MPI) advice on how to ensure formula is free from contamination or tampering. Their advice to consumers is that if any food product appears to have been tampered with – for example, seals broken or punctured – then it should not be consumed and it should be reported to the Police on 0800 723 665. Further advice is available on this web link: www.foodprotection.govt.nz/for-consumers/ways-to-check-for-tampering

Keeping your baby or child and yourself safe

- You may wish to provide the parents with the *Feeding your baby infant formula* information sheet compiled by the Ministry of Health and Ministry for Primary Industries. This can be downloaded from the website: www.foodprotection.govt.nz/for-consumers
- The ability for anybody to deliberately contaminate infant and other formula during manufacturing is very low. There is no evidence this has occurred.
- New Zealand formula is safe to consume at the time of manufacture and distribution – either for retail in New Zealand or export.
- The Ministry for Primary Industries (MPI) have put a new 1080 testing regime in place that gives the Government a high degree of confidence that the products covered by the threat do not contain traces of 1080.

- To further protect the products, infant formula and other formula products are usually sold in tamper-evident packaging, which is designed to help you see if someone has opened or interfered with the packaging.
- Parents should follow Ministry for Primary Industries (MPI) advice on how to ensure formula is free from contamination or tampering. Their advice to consumers is that if any food product appears to have been tampered with – for example, seals broken or punctured – then it should not be consumed and it should be reported to the Ministry for Primary Industries on 0800 008 333 or info@nzfoodinfo.govt.nz. This advice will be available on this web link: www.foodprotection.govt.nz/for-consumers/ways-to-check-for-tampering/

1080 (fluoroacetate)

- 1080 is a pesticide used on targeted pests in New Zealand.
- It is **highly toxic** to humans.
- Fluoroacetate is a white, tasteless and odourless fine powder that can look like icing sugar or fine salt. Diluted solutions may taste like vinegar.
- The poison acts rapidly and disturbs the production of energy for cells and organs. Toxicity occurs in organs in the body that require a lot of energy (eg, heart, brain, kidneys). As these organs do not receive the energy they require, they begin to fail leading to potentially life-threatening illness.

Presentation of symptoms

- The poison acts rapidly. Depending on the dose ingested, symptoms usually occur within 30 minutes of exposure and progress rapidly. Lower doses may take longer (up to three hours) to produce symptoms.
- A full case definition is available to download from www.health.govt.nz/our-work/environmental-health/contamination-infant-and-other-formula-products/definition-fluoroacetate-1080-poisoning

Infants or children

- Symptoms of ingestion are that of an **unwell** infant or child, and are initially non-specific. Clinicians evaluating a sick child should follow normal assessment and management approaches.
- If the infant or child is **asymptomatic at presentation or four hours after last feed**, and you are confident the child will be adequately observed, it is reasonable to discharge the child home. Please provide the parents with information about recognition of illness. This information is available in the back section and back cover of the *Well Child Tamariki Ora – My Health Book* (Danger Signs – Baby and Child Sickness) and can be downloaded from the following website: https://www.healthed.govt.nz/resource/well-child-tamariki-ora-my-health-book
- If a child is mildly unwell, has been symptomatic for several hours but is **not** becoming progressively worse, it is extremely unlikely that this illness is due to fluoroacetate poisoning. Other diagnoses need to be considered, investigated and managed accordingly.

- The early and late signs of fluoroacetate poisoning are shown below.

Early signs	Irritable or inconsolable
	Rapid shallow breathing
	Abdominal pain
	Vomiting
	Flushed cheeks
	Sweaty
	Pale and apprehensive
	Glazed eyes and not focusing on anything
Late signs	Collapse or unresponsiveness
	Seizures

Adults

- Symptoms of ingestion are that of an **unwell** adult, and are initially non-specific. Clinicians evaluating an unwell adult should follow standard assessment and management clinical pathways.
- If the patient is **asymptomatic at presentation or four hours after consumption of the formula**, and you are confident the patient will be adequately observed, it is reasonable to discharge the person for 24-hour home observation. It is important the key home care carer/observer is fully briefed about warning symptoms and signs indicating 1080 poisoning and should have a low threshold for seeking ED review on suspicion.
- If an adult is mildly unwell, has been symptomatic for several hours but is **not** becoming progressively worse, it is extremely unlikely that this illness is due to fluoroacetate poisoning. Other diagnoses need to be considered in the differential diagnosis. The decision to pursue 1080 testing is subject to the judgement of the treating clinician.
- The early and late signs of fluoroacetate poisoning are shown below.

Early signs	Apprehension and agitation
	Rapid shallow breathing
	Abdominal pain
	Vomiting
	Flushed cheeks
	Sweaty
	Pale and apprehensive
	Glazed eyes and not focusing on anything
Late signs	Confusion and decreasing level of consciousness
	Coma
	Seizures

Initial management of suspected fluoroacetate poisoning

- If you are concerned a patient is seriously unwell call 111 emergency services
- There is **no antidote** for fluoroacetate poisoning.
- Management of suspected poisoning is **supportive** and requires hospital level care. Prompt referral (eg, to emergency medicine specialists or paediatric services) and transfer is paramount as other potential causes of presentation need to be investigated.
- **Do not** induce vomiting. As fluoroacetate is readily absorbed into the body after ingestion, inducing vomiting will not help to decrease toxicity and in fact may cause more harm due to aspiration or choking.
- Benefits from activated charcoal are not proven and it is **NOT recommended that this be used outside of a hospital setting** due to risk of aspiration.

Infants or children

- If possible, please ask the family to keep the suspect infant formula in a safe place, away from further human or animal contact, so further testing can be done if needed.
- If parents bring the suspect formula with them, please handle it as little as possible, place in a clean cardboard box, store it securely and label it with the child's admission label. The police may request the formula for forensic examination.
- You may wish to provide the *Feeding your baby infant formula* information sheet compiled by the Ministry of Health and Ministry for Primary Industries. This can downloaded from the website: www.foodprotection.govt.nz/for-consumers
- Please ask the family to bring the child back to the emergency department for assessment if the child has any of the symptoms. If transport issues are present or the child becomes more unwell, advise them that a '111' Emergency Services call should be made.

Adults

- If possible, please ask the individual or others to keep the suspect formula in a safe place, away from further human or animal contact, so further testing can be done if needed.
- If individuals bring the suspect formula with them, please handle it as little as possible, place in a clean cardboard box, store it securely and label it with the patient's admission label. The police may request the formula for forensic examination.

MINISTRY OF HEALTH
MANATŪ HAUORA

HP6157

Suspected 1080 (Fluoroacetate) Ingestion from Contaminated Infant Formula or Other Formula

Guidance for secondary care (emergency departments and acute paediatric services)

17 March 2015

1080 (fluoroacetate)

Clinicians should familiarise themselves with the TOXINZ fact sheet on fluoroacetate poisoning available to download from www.toxinz.com

In summary:

- 1080 (fluoroacetate) is a pesticide used on targeted pests in New Zealand.
- It is **highly toxic** to humans.
- Fluoroacetate is a white, tasteless and odourless fine powder that can look like icing sugar or fine salt. Diluted solutions may taste like vinegar.
- Fluoroacetate is readily absorbed and metabolised to fluorocitrate which acts rapidly to disturb the citric acid (Krebs) cycle. The poison competitively inhibits enzyme activity in oxidative metabolism, leading to accumulation of citrate and lactate. This results in a metabolic acidosis and electrolyte abnormalities (hypocalcaemia, hypokalaemia). Hyperkalaemia may develop if renal function is affected.
- Indirectly, by stopping the citric acid (Krebs) cycle, fluorocitrate also disrupts the urea cycle by inhibiting glutamate production, leading to a build-up of ammonia.
- Metabolically active tissues, such as cardiac, renal or neural tissue, are critically affected leading to multi-organ failure, while biochemical imbalances lead to further morbidity.

Information on testing of infant and other formula

- You may wish to provide the parents with the *Tampering* information sheet compiled by the Ministry for Primary Industries (MPI) available on this web link: www.foodprotection.govt.nz/for-consumers/ways-to-check-for-tampering
- The ability for anybody to deliberately contaminate infant and other formula during manufacturing is very low. There is no evidence this has occurred.
- New Zealand formula is safe to consume at the time of manufacture and distribution – either for retail in New Zealand or export.
- The Ministry for Primary Industries (MPI) have put a new 1080 testing regime in place that gives the Government a high degree of confidence that the products covered by the threat do not contain traces of 1080.
- To further protect the products, infant formula and other formula products are usually sold in tamper-evident packaging, which is designed to help you see if someone has opened or interfered with the packaging.

- Consumers should follow Ministry for Primary Industries (MPI) advice on how to ensure formula is free from contamination or tampering. Their advice to consumers is that if any food product appears to have been tampered with – for example, seals broken or punctured – then it should not be consumed and it should be reported to the Police on 0800 723 665. Further advice is available on this web link: www.foodprotection.govt.nz/for-consumers/ways-to-check-for-tampering

Presentation of symptoms

- The poison acts rapidly. Depending on the dose ingested, symptoms usually occur within 30 minutes of exposure and progress rapidly. Lower doses may take longer (up to three hours) to produce symptoms.
- A full case definition is available to download from www.health.govt.nz/definition-fluoroacetate-1080-poisoning

Infants or children

- Symptoms of ingestion are that of an **unwell** infant or child, and are initially non-specific. Clinicians evaluating a sick child should follow normal assessment and management approach.
- If the infant or child is **asymptomatic at presentation or four hours after last feed**, and you are confident the child will be adequately observed, it is reasonable to discharge the child home. Please provide the parents with information about recognition of illness. This information is available in the back section and back cover of the *Well Child Tamariki Ora – My Health Book* (Danger Signs – Baby and Child Sickness) and can be downloaded from: https://www.healthed.govt.nz/resource/well-child-tamariki-ora-my-health-book
- If a child is mildly unwell, has been symptomatic for several hours but is **not** becoming progressively worse, it is extremely unlikely that this illness is due to fluoroacetate poisoning. Other diagnoses need to be considered, investigated and managed accordingly.
- The early and late signs of fluoroacetate poisoning are shown below.

Early signs	Irritable or inconsolable
	Rapid shallow breathing
	Abdominal pain
	Vomiting
	Flushed cheeks
	Sweaty
	Pale and apprehensive
	Glazed eyes and not focusing on anything
Late signs	Collapse or unresponsiveness
	Seizures

Adults

- Symptoms of ingestion are that of an **unwell** adult, and are initially non-specific. Clinicians evaluating an unwell adult should follow normal assessment and management approaches.
- If the patient is **asymptomatic at presentation or four hours after consumption of the formula**, and you are confident the patient will be adequately observed, it is reasonable to discharge for 24-hour home observation. Please provide adult patients with information about recognition of illness.
- If an adult is mildly unwell, has been symptomatic for several hours but is **not** becoming progressively worse, it is extremely unlikely that this illness is due to fluoroacetate poisoning. Other diagnoses need to be considered, investigated and managed accordingly.
- The early and late signs of fluoroacetate poisoning are shown below.

Early signs	Apprehension and agitation
	Rapid shallow breathing
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	Vomiting
	Flushed cheeks
	Sweaty
	Pale and apprehensive
	Glazed eyes and not focusing on anything
Late signs	Confusion and decreasing level of consciousness
	Coma
	Seizures

Initial management of suspected fluoroacetate poisoning

- There is **no antidote** for fluoroacetate poisoning.
- Management of suspected poisoning is **supportive** and requires hospital level care. Prompt referral and transfer is paramount as other potential causes of presentation need to be investigated.
- **Do not** induce vomiting. As fluoroacetate is readily absorbed into the body after ingestion, inducing vomiting will not help to decrease toxicity and in fact may cause more harm due to aspiration or choking.
- Benefits from activated charcoal are not proven and it is **NOT recommended that this be used outside of a hospital setting** due to risk of aspiration.
- Clinicians are reminded that section 74 of the Health Act 1956 requires medical practitioners to **notify medical officers of health** of cases of listed notifiable diseases, in particular acute gastroenteritis and poisoning arising from chemical contamination of the environment. A notification requirement is also mandated under section 143 of the Hazardous Substances and New Organisms Act 1996 requiring hospitals and medical practitioners to notify hazardous substances injuries to medical officers of health.
- Medical practitioners are asked to urgently notify their medical officer of health of possible, probable or confirmed cases of fluoroacetate (1080) poisoning by phone, fax, email or via the

Hazardous Substances Disease and Injury Reporting Tool (HSDIRT) included in bestpractice decision support (BPAC), My Practice and Profile for Windows patient management systems (https://www.bestpractice.org.nz).

- Medical officers of health are asked to urgently inform the Ministry of Health of suspected or confirmed cases.

Infants or children

- If possible, please ask the family to keep the suspect infant formula in a safe place, away from further human or animal contact, so further testing can be done if needed.
- If parents bring the suspect formula with them, please handle it as little as possible, place in a clean cardboard box and store it securely and label it with the child's admission label. The police may request the formula for forensic examination.
- You may wish to provide the *Feeding your baby infant formula* information sheet compiled by the Ministry of Health and Ministry for Primary Industries. This will be available for download from the website: www.foodprotection.govt.nz/for-consumers
- Please ask the family to bring the child back to the emergency department for assessment if the child has any of the symptoms stated on the back of the Well Child Book. If transport issues are present or the child becomes more unwell, advise them that a '111' Emergency Services call should be made.

Adults

- If possible, please ask the individual or others to keep the suspect formula in a safe place, away from further human or animal contact, so further testing can be done if needed.
- If individuals bring the suspect formula with them, please handle it as little as possible, place in a clean cardboard box, store it securely and label it with the patient's admission label. The police may request the formula for forensic examination.

Investigations

- A urine test for fluoroacetate is available. See over the page for protocol. Since there is no antidote management is symptomatic.
- If fluoroacetate poisoning is suspected, a **blood gas** should be performed. Due to fluoroacetate disrupting the early phases of the citric acid (Krebs) cycle, **a metabolic (lactic) acidosis with high anion gap** should be evident with **possible respiratory compensation**.

Children

- Children unwell with symptoms and signs similar to fluoroacetate poisoning but with **NORMAL lactate levels makes fluoroacetate toxicity very unlikely**. Since critically unwell children usually have elevated lactate levels due to poor tissue perfusion, **other differential diagnoses** (eg, acute diabetic ketoacidosis, other metabolic disorders, sepsis, or toxicity with other substances), should be considered, investigated and managed accordingly. Advice from your local paediatric medicine specialists, intensive care medicine specialists and Starship sub-specialties should be sought.

Adults

- Adults unwell with symptoms and signs similar to fluoroacetate poisoning but with **NORMAL lactate levels makes fluoroacetate toxicity very unlikely**. Since critically unwell adults

usually have elevated lactate levels due to poor tissue perfusion, **other differential diagnoses** (eg, acute diabetic ketoacidosis, other metabolic disorders, sepsis, or toxicity with other substances), should be considered, investigated and managed accordingly. Advice from your local **intensive care or emergency medicine specialists should be sought.**

For children and adults

- Investigations and findings in managing suspected fluoroacetate poisoning include the following.

Investigations	Clinical manifestations
Continuous cardiac monitoring, 12-lead ECG	Monitor for arrhythmias (eg, supraventricular and ventricular tachycardias, QT prolongation)
Non-invasive blood pressure monitoring	Hypotension
Blood gas	Metabolic (lactic) acidosis +/- respiratory compensation
Blood ketones	Raised ketone levels leads to worsening acidosis
Serum biochemistry with Ca2+/PO43-/Mg2+	Hyperkalaemia/hypokalaemia, hypocalcaemia, hypomagnesaemia, acute renal failure
Ammonia	Reduced urea cycle function and accumulation of ammonia
Liver functions	Raised transaminases from direct hepatotoxicity
Catheter/clean catch urine	Urine organic acids (citrate), monitor urine output for acute renal failure (also send for culture)
Full blood count + blood culture	To investigate possible underlying infection or other abnormalities

Protocol for sending urine specimens for analysis

- Please urgently contact LabPlus to advise that specimens for urgent analysis for suspected fluoroacetate poisoning are being collected. Phone: Michelle Blake, LabPlus Specimen Services on 021 913 244.
- Urine specimens should be collected and labelled as for any other routine specimen; no special containers or reagents are required to preserve the specimen.
- A minimum of 10 ml of urine is required. The sample should kept refrigerated (approx. 5°C) until dispatch and should be frozen (-10°C) if they are to be stored longer than one day.
- Samples should be urgently dispatched to LabPlus, marked: 'urgent analysis required' (or as directed by LabPlus). Using appropriate IATA packaging.
- The courier address is:
  LabPLUS
  Building 31, Auckland City Hospital
  Gate 4 off Grafton Rd
  Grafton, Auckland
- Please confirm specimen dispatch, including relevant specimen identification and courier details, by email: michellebl@adhb.govt.nz or phone: 021 913 244.

- Results will generally be available within 24–48 hours from receipt in the testing laboratory dependent upon delivery time and sample numbers.
- **Do not send milk or milk powder to LabPlus.**

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New Zealand Government

Suspected 1080 (Fluoroacetate) Ingestion from Contaminated Infant Formula or other Formula

Guidance for Healthline and PlunketLine nurses

17 March 2015

Infant & child feeding

Key points for parents

- Infants under one year of age should be breastfed, or fed with a properly prepared, commercial dairy or soy based infant formula.
- Mothers who have stopped breastfeeding recently may be able to restart breastfeeding again with help from their midwife, lactation consultant, general practitioner or Well Child nurse.
- Exclusively or fully breastfed infants are **not** at risk of formula contamination.
- The Ministry of Health does **not** recommend that parents feed infants **under one year of age** pasteurised whole or homogenised cow's milk, or prepare home-made alternatives to infant formula.
- If your baby is on a special formula because of food allergy or special dietary requirements, do **not** change your formula without consulting with a dietitian, paediatrician or general practitioner.
- You should follow Ministry for Primary Industries (MPI) advice on how to ensure formula is free from contamination or tampering. Their advice to consumers is that if any food product appears to have been tampered with – for example, seals broken or punctured – then it should not be consumed and it should be reported to the Police on 0800 723 665. Further advice is available on this web link: www.foodprotection.govt.nz/for-consumers/ways-to-check-for-tampering

Keeping your baby/child safe

- You may wish to provide the parents with the *Feeding your baby infant formula* information sheet compiled by the Ministry of Health and Ministry for Primary Industries. This can be downloaded from the website: www.foodprotection.govt.nz/for-consumers
- The ability for anybody to deliberately contaminate infant and other formula during manufacturing is very low. There is no evidence this has occurred.
- New Zealand formula is safe to consume at the time of manufacture and distribution – either for retail in New Zealand or export.
- The Ministry for Primary Industries (MPI) has put a new 1080 testing regime in place that gives the Government a high degree of confidence that the products covered by the threat do not contain traces of 1080.
- To further protect the products, infant formula and other formula products are usually sold in tamper-evident packaging, which is designed to help you see if someone has opened or interfered with the packaging.

- Parents should follow Ministry for Primary Industries (MPI) advice on how to ensure formula is free from contamination or tampering. Their advice to consumers is that if any food product appears to have been tampered with – for example, seals broken or punctured – then it should not be consumed and it should be reported to the Ministry for Primary Industries on 0800 008 333 or info@nzfoodinfo.govt.nz. This advice will be available on this web link: www.foodprotection.govt.nz/for-consumers/ways-to-check-for-tampering

1080 (fluoroacetate)

- 1080 is a pesticide used on targeted pests in New Zealand.
- It is **highly toxic** to humans.
- Fluoroacetate is a white, tasteless and odourless fine powder that can look like icing sugar or fine salt. Diluted solutions may taste like vinegar.
- The poison acts rapidly and disturbs the production of energy for cells and organs. Toxicity occurs in organs in the body that require a lot of energy (eg, heart, brain, kidneys). As these organs do not receive the energy they require, they begin to fail leading to potentially life-threatening illness.

Presentation of symptoms

- The poison acts rapidly. Depending on the dose ingested, symptoms usually occur within 30 minutes of exposure and progress rapidly. Lower doses may take longer (up to three hours) to produce symptoms.
- A full case definition is available to download from www.health.govt.nz/our-work/environmental-health/contamination-infant-and-other-formula-products/definition-fluoroacetate-1080-poisoning

Infants or children

- Symptoms of ingestion are that of an **unwell** infant or child, and are initially non-specific. Clinicians evaluating a sick child should follow normal assessment and management approaches.
- If the infant or child is **asymptomatic at presentation or four hours after last feed**, and you are confident the child will be adequately observed, it is reasonable to discharge the child home. Please provide the parents with information about recognition of illness. This information is available in the back section and back cover of the *Well Child Tamariki Ora – My Health Book* (Danger Signs – Baby and Child Sickness) and can be downloaded from the following website: https://www.healthed.govt.nz/resource/well-child-tamariki-ora-my-health-book
- If a child is mildly unwell, has been symptomatic for several hours but is **not** becoming progressively worse, it is extremely unlikely that this illness is due to fluoroacetate poisoning. Other diagnoses need to be considered, investigated and managed accordingly.

- The early and late signs of fluoroacetate poisoning are shown below.

Early signs	Irritable or inconsolable
	Rapid shallow breathing
	Abdominal pain
	Vomiting
	Flushed cheeks
	Sweaty
	Pale and apprehensive
	Glazed eyes and not focusing on anything
Late signs	Collapse or unresponsiveness
	Seizures

Adults

- Symptoms of ingestion are that of an **unwell** adult, and are initially non-specific. Clinicians evaluating an unwell adult should follow standard assessment and management clinical pathways.
- If the patient is **asymptomatic at presentation or four hours after consumption of the formula**, and you are confident the patient will be adequately observed, it is reasonable to discharge for 24-hour home observation. It is important the key home care carer/observer is fully briefed about warning symptoms and signs indicating 1080 poisoning and should have a low threshold for seeking ED review on suspicion.
- If an adult is mildly unwell, has been symptomatic for several hours but is **not** becoming progressively worse, it is extremely unlikely that this illness is due to fluoroacetate poisoning. Other diagnoses need to be considered in the differential diagnosis. The decision to pursue 1080 testing is subject to the judgement of the treating clinician.
- The early and late signs of fluoroacetate poisoning are shown below.

Early signs	Apprehension and agitation
	Rapid shallow breathing
	Abdominal pain
	Vomiting
	Flushed cheeks
	Sweaty
	Pale and apprehensive
	Glazed eyes and not focusing on anything
Late signs	Confusion and decreasing level of consciousness
	Coma
	Seizures

Management of a child or adult with suspected 1080 poisoning

- There is no antidote for 1080 poisoning.
- If you are concerned a child or adult is seriously unwell, call '111' Emergency Services immediately.
- Management of suspected poisoning is **supportive** and requires hospital level care.
- **Do not** induce vomiting. As 1080 is readily absorbed into the body after ingestion, inducing vomiting is unlikely to decrease toxicity and in fact may cause more harm due to aspiration or choking.
- Activated charcoal is **not** recommended outside of a hospital setting due to risk of aspiration.
- Call local emergency medicine specialists or paediatric services if you have concerns regarding infants who may be showing symptoms/signs of 1080 poisoning.
- Clinicians are reminded that section 74 of the Health Act 1956 requires medical practitioners to **notify medical officers of health** of cases of listed notifiable diseases, in particular acute gastroenteritis and poisoning arising from chemical contamination of the environment. A notification requirement is also mandated under section 143 of the Hazardous Substances and New Organisms Act 1996 requiring hospitals and medical practitioners to notify hazardous substances injuries to medical officers of health.
- Medical practitioners are asked to urgently notify their medical officer of health of possible, probable or confirmed cases of fluoroacetate (1080) poisoning by phone, fax, email or via the Hazardous Substances Disease and Injury Reporting Tool (HSDIRT) included in bestpractice decision support (BPAC), My Practice and Profile for Windows patient management systems (https://www.bestpractice.org.nz).
- Medical officers of health are then asked to urgently inform the Ministry of Health of suspected or confirmed cases.
- Please ask the family to keep the suspect infant formula in a safe place at home, away from further human or animal contact, in case it is required for further testing.

MINISTRY OF HEALTH
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Background information on 1080 use in New Zealand

Properties and use of 1080

The chemical name for 1080 is sodium monofluoroacetate, although it is commonly known as 1080, the number designated to it when it was being assessed as a rodenticide in the USA in the 1940s. It has been used in New Zealand for pest control since the 1950s. Since its discovery, monofluoroacetate has been identified as the toxic agent in many poisonous plants native to Brazil and South and West Africa. Monofluoroacetate also occurs naturally in some 40 plant species in Australia.

New Zealand is currently the world's largest user of 1080 poison for controlling vertebrate pests, primarily possums, rabbits, rats, mice and stoats. New Zealand uses between 1 – 3.5 tonnes per annum which is about 80% of the world total. All of the 1080 used in New Zealand originates from one manufacturer in the United States (Tull Chemical Company Incorporated). Import of 1080 for manufacturing pest control baits is strictly regulated.

Most of the 1080 used in New Zealand is incorporated into cereal pellets at a rate of 0.15% and used for possum control. The consumption of one bait is normally lethal for a possum. Carrot, paste and gel baits are also used.

1080 use has been and continues to be extensively researched to reduce its risks and improve targeting to pest species. For example, 30 years ago a standard operation used around 30kg of un-dyed carrot bait per hectare. Today thanks to better understanding of pest control a standard operation would use between 1.5kg and 3kg of dyed cereal bait.

Reasons for using 1080

Conservation

New Zealand's plants, birds, reptiles, snails and insects have evolved over tens of millions of years without ground-based predators. Human colonisation of New Zealand introduced a range of mammalian species, including rats, brushtailed possums, stoats and mice.

Our flora and fauna have not needed defence mechanisms against these introduced mammalian species, prior to their introduction, and are highly vulnerable to exotic tree climbing predators and herbivores in particular. Predators are blamed for an estimated 60% (approximately 26.5 million) of chick and egg losses every year.

A range of native species are preyed upon by introduced predators these include species that are:

- in immediate danger of extinction: mohua (yellowhead), southern New Zealand dotterel and kakariki (parakeet),
- acutely threatened: Rowi/Okarito brown kiwi, kaka and North Island kokako,
- nationally critical: several species of giant New Zealand snail, *Powelliphanta*.

Introduced pests have also devastated our forest canopy and stripped vast tracts of native bush. Forest trees and plants such as rata, kamahi, pohutukawa, mistletoe and fuchsia are particularly badly affected.

The New Zealand Conservation Department uses 1080 on a range of conservation lands that include off shore islands, forests, shrub lands and alpine areas. Many of these areas are remote and not easily accessible for other methods of pest control. There has been a recent temporary increase in the use of 1080 for conservation purposes linked to an explosion in the population of rats and mice and their predators.

TB vector control

In addition the Australian brushtail possum is the primary vector for the serious cattle disease, bovine tuberculosis. Effective control of possums by TBFree New Zealand has progressively reduced the numbers of infected herds throughout New Zealand, in the past decade by more than 90%, and eradicated the disease from some areas.

Benefits of 1080

Although pest control agencies use a variety of trapping and hand laying of different poisons, the aerial spreading of 1080 laced cereal pellets is used in steep and inaccessible area of forests and other areas adjacent to farmlands. Aerial 1080 operations involving pre-feeding of baits are reliable in achieving high kills not only of possums but also rats and stoats. This control of the three major bird predators over a large area provides a breeding 'window' that is crucial to increasing female and chick survival. A large number of case studies show the recovery of native species after a 1080 operation.

Humaneness of 1080

Use of any type of toxin involves ethical issues and trade-offs, for example with regard to its humaneness relative to its effectiveness and also the suffering target pests inflict on their prey.

The period between the time 1080 is eaten and the appearance of symptoms of poisoning in mammals is between 0.5 and 3 hours. Animals receiving small sub-lethal doses of 1080 show mild signs of poisoning, metabolise and excrete 1080 within 1–4 days, and then recover. After a lethal dose possums usually die within 6–18 hours.

Regulation of 1080

1080 is regulated in New Zealand as a Hazardous Substance by the New Zealand Environmental Protection Agency (EPA) and as a vertebrate toxic agent by the Ministry for Primary Industries (MPI).

EPA regulation

In 2007 the predecessor organisation of the EPA undertook a rigorous, comprehensive review of 1080, including a series of nationwide public hearings. All interested parties were invited to present written and oral submissions to an independent committee. The committee spent four months of intensive deliberation, which included an independent analysis of all the scientific data. ERMA

concluded that the benefits of using 1080 clearly outweighed the risks, and approved its continued use in aerial and ground applications, subject to strict controls.
These controls include requiring all users of 1080 to hold a controlled substance licence and track its use, requiring detailed signage to remain up around any 1080 operation for public guidance and annual reporting of all aerial operations and any adverse events.

Worksafe New Zealand is the enforcement agency for the EPA. It is the role of Worksafe New Zealand to ensure that all operators are approved handlers and meet all EPA requirements around the use of 1080.

MPI regulation

MPI registers all 1080 products for use in New Zealand as approved vertebrate toxic agents. The registration process for vertebrate toxic agents assesses all aspects of risk of residues in the food supply, animal welfare and product efficacy. All facilities manufacturing 1080 products have to be approved.

To ensure 1080 is being used correctly and does not represent a risk to the commercial food supply MPI undertakes residue testing of wild animals, livestock and milk.

MPI has tested farmed and wild animals for 1080 residues since 1999 under the National Chemical Residues Programme. All the test results from these programmes have been negative. MPI considers that the current residue monitoring of wild animals and periodic surveillance of farmed animals is sufficient to detect potential residue problems.

Other government reviews

In 2011 the use of 1080 in New Zealand was reviewed by the Parliamentary Commissioner for the Environment (PCE). The overview to this report ends with the following paragraphs:

"It is my view based on careful analysis of the evidence that not only should the use of 1080 continue (including in aerial operations) to protect our forests, but that we should use more of it. And it is not as if much is being used now. Currently there is more Crown funding given to the Animal Health Board to kill carriers of bovine TB than the Department of Conservation spends on controlling possums, rats and stoats over the entire conservation estate.

It is seldom that I come to such a strong conclusion at the end of an investigation. But the possums, rats and stoats that have invaded our country will not leave of their own accord. Much of our identity as New Zealanders, along with the clean green brand with which we market our country to the world, is based on the ecosystems these pests are bent on destroying. We cannot allow our forests to die."

20 January 2015

Risk assessment of sodium monofluoroacetate (compound 1080) in some New Zealand dairy products

Purpose of this risk assessment:

This risk assessment was developed as a result of a New Zealand dairy company and the New Zealand Federated Farmers organisation receiving a threat of potential contamination of infant and other dairy formula products with compound 1080.

Toxicology:

There have been several studies published in the scientific literature reporting on various aspects of compound 1080 toxicology in mammals. The most definitive was of a 90-day toxicological evaluation of compound 1080 in rats (Eason and Turck, 2002). The outcomes of this study were consistent with other published studies and so there is a good database of toxicological data that allows the determination of a reference health standard (RHS) for compound 1080 for use in this assessment. (The reference health standard is the dose of 1080 that can be consumed over a period of time without adverse effect on the consumer).

Compound 1080 is essentially an acute toxin, but does have some identified longer term toxicity that on male testes and heart, both of which have a clear No Observed Adverse Effect Level (NOAEL) which is the dietary exposure that needs to be exceeded for toxic effects to be seen. The toxic effects also show clear signs of being reversible once exposure ceases and that the identified toxicity has a steep dose-response curve. The study also showed that the level of 1080 in serum did not increase over time.

The NOAEL determined by Eason and Turck is 0.075 mg/kg bw per day. The tolerable daily intake is determined from this NOAEL by dividing by a suitable uncertainty factor which takes into account the robustness of the data, the seriousness and reversibility of any effects seen, and the fact that the data needs to be extrapolated from animals to humans. The study was very thorough and done in accordance with the requirements of the US Environmental Protection Agency Guidelines (that closely mirror those of the OECD) and the data is therefore robust. The NOAELs are clear and the toxicity outcomes reversible and subject to a steep dose-response curve. The population determined to be the most sensitive and present the potential worst case scenario is of infants and so the appropriate uncertainty factor to be applied was determined to be 500 (10 for interspecies variation, 10 for intraspecies variation, and 5 for taking infants into account). Further comment on the uncertainty factors is included in the discussion of the differences between this risk assessment and others that have been published.

On the basis of an uncertainty factor of 500, the RHS was determined to be 0.075/500 = 0.00015 mg/kg bw per day (= 0.15 µg/kg bw per day).

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Discussion of the differences in other risk assessments of compound 1080:

We are aware that there are other derivations of referenced health standards [variously termed tolerable daily intake (TDI) or acceptable daily intake (ADI)] that differ from the RHS derived in this assessment. Some of these have been derived prior to the publication of the study that informed this assessment, and others have used uncertainty factors that differ from those used here. The determination of the uncertainty factors to use in any risk assessment is made by individual risk assessors. To enable the determination of the robustness of this risk assessment, the uncertainty factors used are clearly stated. They essentially differ in two ways from other assessments we are aware of as detailed below:

Firstly, we have not used an additional factor of 10 because of an inadequate database because we are aware that there are other equivalent studies to the 90-day study used in this assessment, and they are consistent in their findings. There are other studies of different toxicological end points that lead us to conclude that this factor was not necessary.

Other 90-day studies administered different doses of compound 1080, and hence because the actual dose at which toxicity begins to manifest itself in any study lies somewhere between the NOAEL and the LOAEL, the other studies established different NOAELs (and therefore developed different reference health standards). However, the studies are consistent in that each NOAEL is below the lowest observed adverse effect level (LOAEL) seen in any of the studies and all NOAELs are therefore equally valid, with the highest being closest to the actual dose at which toxicity just begins to occur.

Foronda et al used benchmark dose benchmark dose approach to determine an actual point of departure on the dose response curve. This concluded that the most appropriate dose level for determining the TDI was 0.1 mg/kg bw per day, which compares well with and supports the 0.075 mg/kg bw per day used in this assessment.

Secondly, we did not use an additional factor because of the lack of chronic toxicity data which meant that we used the sub-chronic 90-day study. We determined that this was not necessary because the toxic effects of 1080 are more acute than developing over a long term, and Eason and Turck showed that the affects demonstrated reversibility, and that compound 1080 is quickly eliminated from the body after intake. Further, the likely human exposure in the scenario being considered here would be only for a very short part of their lifetime while the RHS does apply to longer term exposure (the 90-day rat study equates to approximately 10 human years). Therefore we consider that the 90-day study more than adequately modelled the likely human exposure in this case.

In addition to the above, we used an additional factor to take into account the potential that an exposure could be to an infant, even though the mode of action for 1080 is via inhibition of a metabolic pathway that is fully operational in infants as well as adults and there may not be any difference in sensitivity. We used the additional factor because we could not find any data that confirmed a lack of difference and so we assumed that infants are more vulnerable.

6(c), 9(2)(c)

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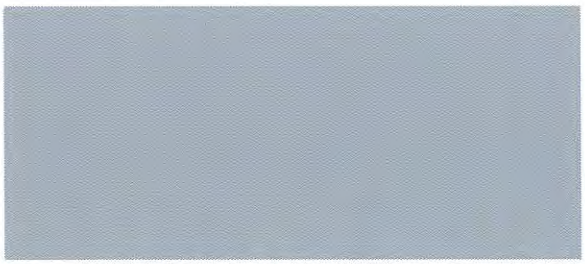

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