



Environmental  
Protection Authority  
Te Mana Rauhi Taiao

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# Flexible Reassessment Categorisation Screening Tool (FRCaST) support notes

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## Screening and prioritisation of chemicals for review

October 2018

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## Executive Summary

The Environmental Protection Authority Te Mana Rauhi Taiao (EPA) faces the challenge of identifying chemicals that it considers to be a high priority for review, to ensure that measures are taken to reduce the risks associated with use of those chemicals.

This report provides supplementary information on the creation of the EPA's Priority Chemicals List. It details the approach taken by the EPA to identify chemicals of concern, with a view to informing the development of the EPA's Reassessment Work Plan. Specifically, this report discusses the development of FRCaST (Flexible Reassessment Categorisation Screening Tool) as well as providing an overview of how FRCaST works.

The EPA has developed FRCaST to quickly screen chemicals of interest in order to identify whether they should be a priority chemical (that is, a chemical that should be considered for inclusion on the Reassessment Work Plan).

FRCaST takes a risk-based approach to screening by qualitatively attributing risk scores for different use scenarios of chemicals, based on hazards of the substance and exposures associated with those uses. FRCaST then assigns a chemical into banded Priority Groups based on the use scenario that scores highest. In addition to the hazard and exposure information, FRCaST gives extra weight to four key factors: use in and around the home, bioaccumulation, persistence, and endocrine disruption.

Screening is intended to allow comparison between chemicals, used for different purposes and in different ways. It is primarily intended to be used for the purposes of prioritisation and work plan development. It is not intended to replace the comprehensive assessments that the EPA undertakes as part of its reassessment work.

FRCaST is only one of the ways the EPA will be identifying chemicals for reassessment. The EPA will continue to watch for emerging issues to see how overseas regulatory decisions could impact the hazardous substances approved in New Zealand, and to maintain up-to-date classifications of those hazardous substances.

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## 1. Introduction

1.1. Hazardous substances in New Zealand need an approval from the Environmental Protection Authority Te Mana Rauhi Taiao (EPA) under the Hazardous Substances and New Organisms (HSNO) Act 1996 before they can be imported into or manufactured in New Zealand. There are approximately 9,000 approvals and 210 Group Standards, addressing well over 150,000 products. The HSNO Act provides a mechanism for the review and amendment of hazardous substance approvals when new information becomes available about the effects of those hazardous substances.

1.2. As new information is constantly being generated from a variety of sources, the challenge is to identify the highest priority chemicals for which the EPA should take action to reduce their associated risks.

1.3. This document describes the approach taken to facilitate the screening of chemicals to identify those that are of concern and for which regulatory action should be taken.

## 2. The philosophy behind FRCaST

2.1. FRCaST (Flexible Reassessment Categorisation Tool) has been developed to provide standardised, risk-informed screening of chemicals.

2.2. FRCaST is used to carry out screening of a high number of chemicals of interest. The results from FRCaST are used to select those hazardous substances in the EPA's Priority Chemicals List. The Priority Chemicals List will be used to inform selection and prioritisation of chemicals into the EPA's Reassessments Work Plan. Furthermore, a Screened Chemical List will be maintained consisting of all the substances screened by the FRCaST tool. Both lists are easily updated if new information arises in the future.

2.3. A key aspect of FRCaST is that it is a risk-based screening tool, taking both hazard and exposure into account. FRCaST uses a qualitative approach to determine a 'score' that is used to categorise the chemical. This allows chemicals to be screened and categorised based on the available data, and allow comparisons to be made for potentially disparate chemicals.

2.4. FRCaST follows a similar basis to screening approaches used in Australia (Inventory Multi-Tiered Assessment and Prioritisation, IMAP) and the USA (prioritisation under Toxic Substances Control Act, TSCA) for industrial chemicals; taking use patterns and exposures into account, given key consideration to a number of specific chemical properties such as persistence and bioaccumulation.

2.5. FRCaST allows chemicals to be categorised into risk-based 'groups'. This allows new chemicals to be added to groups without affecting the order or position of chemicals within the group. Additionally, categorisation allows us to compare chemicals with different risk drivers.

2.6. Toxicological, ecotoxicological and use data necessary for the models to run have been obtained from a range of publicly available sources and the EPA's internal database. The screening approach allows for new information to be incorporated. Where toxicity data was identified that indicated a greater hazard profile than was held in the EPA's database, this was used for the purposes of screening. This new data will then be considered as chemicals are reassessed.

2.7. As new data and information becomes available, it is important to take this into account as it may impact on the screening results and a chemical's position with the priority groupings. FRCaST can be easily rerun for chemicals taking the new information into account. This may result in a change of screening score

and even the Priority Group categorisation (ie to a higher or lower Priority Group, depending on the nature of the new information).

2.8. The current version of FRCaST (version 1) incorporates feedback received from two international regulators. National Industrial Chemicals Notification and Assessment Scheme (NICNAS), in Australia, and Environment and Climate Change Canada undertook a peer review of our approach to screening, to ensure that FRCaST is fit for purpose and aligns with international practice. In general, the feedback was positive. The reviewers' feedback included comments that the screening approach is aligned with best practice by integrating exposure information at an early stage, is transparent and reproducible, and is practical and fit-for-purpose.

2.9. The feedback included suggestions to adjust the hazard scoring system to better align with the approaches used in Australia, Canada, and other major international jurisdictions.

2.10. Key modifications made in response to these peer reviews include:

- a) simplification of the scoring process
- b) adjustment to the human hazard scoring, giving highest weighting to carcinogenic, reproductive and mutagenic classifications
- c) adjustment of environmental hazard scoring to allow environmental risk scores to better align with human health risk scores
- d) restructuring the tool to allow instant calculations and screening results – this improves the usability of the tool, allowing global changes to be made to all screened chemicals efficiently.

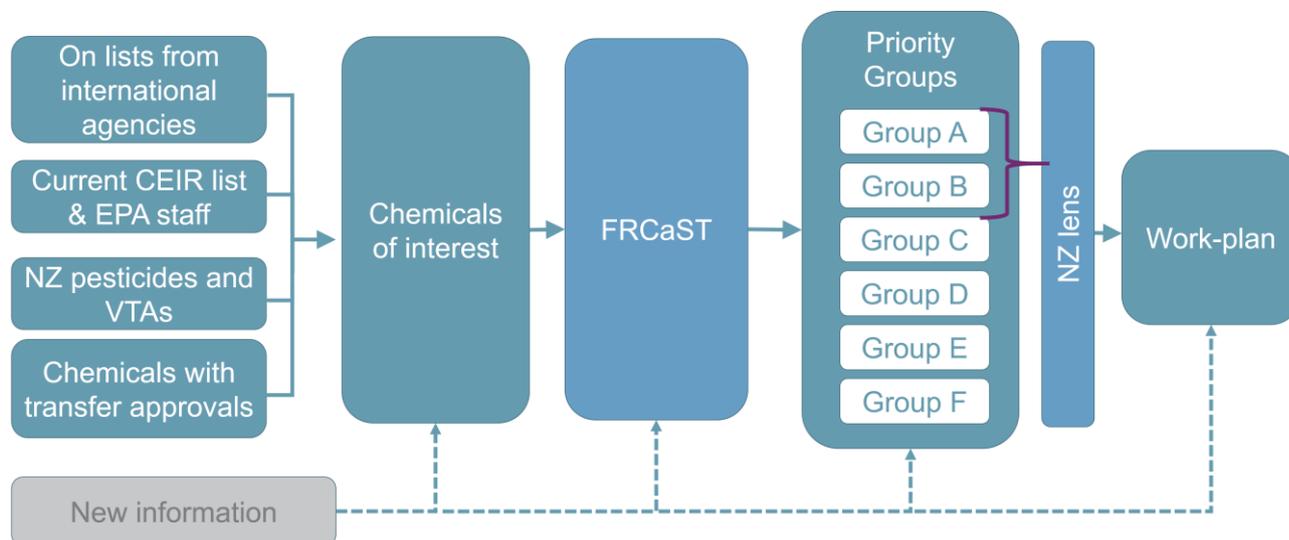
2.11. The feedback included limitations of FRCaST, and of screening approaches in general. These points, with the EPA's response, include:

- a) The lack of use volumes and application rates data as inputs – more research of this nature will be conducted on chemicals that score highly.
- b) The potential for 'data-poor' chemicals to screen lower than they might; the lack of studies on some chemicals may lead to a lack of hazard classifications and hence lower scores – to mitigate this only the HSNO classification with the highest Human Health Hazard Category was taken into account to determine the Human Health Hazard Factor (HHH) – see point 6.19.
- c) The science around categorisation of chemicals with endocrine disrupting properties is far from consensus – we acknowledge this but consider this to be an important factor and have included it in FRCaST as a modifier – see point 6.31.

2.12. In addition, the approach does not fully encompass any existing controls a chemical might have. Any existing controls were taken into account when calculating exposure and would be fully considered as part of any reassessment.

### 3. The screening process and work plan development

3.1. An overview of the overall screening process is presented in Figure 1. FRCaST is one stage of the process for prioritising a chemical for reassessment.



**Figure 1. Overview of the screening process for a reassessment chemical**

3.2. Output of the FRCaST categorisation will inform the EPA's reassessment work-plan. An appraisal of the significance of the level of risk posed by a chemical will be considered when including a chemical on the work-plan. For example, a chemical may have a high potential risk, though there may be minimal use of the substance in New Zealand. Consequently, it may be determined that the risks presented by the chemical are not significant.

3.3. Information on substance use was obtained from the EPA's substance database, as well as publicly available reports from the databases of other international regulators. Information on the volume of chemicals/substances used in New Zealand is not currently available to the EPA and will be requested for chemicals that are being considered for inclusion in the work-plan. When usable data becomes more readily available in the future, the tool will be reviewed to consider whether this information could be incorporated at an early stage in the screening process.

### 4. Identification of chemicals to undergo screening (Inputs)

4.1. There are a number of possible sources for the identification of chemicals to screen, including (but not limited to):

#### *Presence on an overseas list of concern*

4.2. Lists of chemicals developed by major regulatory bodies in Europe, Norway, Canada, Australia and the USA for action in their jurisdictions were the starting point for many chemicals of interest. Recent overseas regulatory action was also a path for inclusion in screening.

#### *EPA CEIR list*

4.3. The last Chief Executive-Initiated Reassessments List was issued by the EPA in 2010. It was intended to be a short list of chemicals with potential to undergo a Chief Executive-initiated reassessment. This list

focussed on the pesticides present in New Zealand in 2004 in large volumes. Where a chemical on the CEIR list had all of its uses reassessed, it has not been considered for screening.

#### *EPA staff suggestions*

4.4. EPA staff members had the opportunity to include chemicals that were of interest to them because of their professional judgement.

#### *New Zealand pesticides*

4.5. A list of pesticide formulations, the 'List of New Zealand Pesticide Active Ingredients', known to be available in New Zealand<sup>1</sup> provided an indication of the active ingredients that were available for use for the agricultural sector. While this source may not be absolutely comprehensive, it provides a starting point for identifying the range of pesticide active ingredients currently in use in New Zealand.

#### *Domestic use VTAs*

4.6. Special effort has been made to include domestic use vertebrate toxic agents (VTAs) in the screening process. This is due to their typically high toxicity and proximity to members of the public.

#### *Chemicals with transfer approvals*

4.7. A large number of chemicals were approved under the HSNO Act because they were already approved in previous legislation that was brought together by the HSNO Act. These chemicals, and formulated hazardous substances, were granted transfer approvals.

4.8. At the time of writing, all chemicals in Table 1 of the Hazardous Substances (Chemicals) Transfer Notice 2006 have been screened. This table includes all pesticides and veterinary medicines granted transfer approval.

#### *Public, media or political interest in particular chemicals*

4.9. The EPA includes chemicals that have significant levels of public, media or political interest as screening inputs.

## 5. Priority Chemicals List and Screened Chemicals List (Outputs)

5.1. Once chemicals of interest have been through the screening process, they will be categorised into risk-driven Priority Groups (A through F).

5.2. The Priority Chemicals List (PCL) is populated by chemicals that have been screened and categorised into the higher risk groups (ie Priority Groups A and B).

5.3. The screening process also populates a number of lower risk groups (C through F), which would not be considered to be of sufficiently high priority to require immediate consideration for inclusion in the EPA's reassessment work plan, and consequently do not contribute to the Priority Chemicals List. Further work, including similarity to Priority Chemicals, may result in chemicals in the lower risk groups being included in the reassessment work-plan. All chemicals that have been screened, regardless of their priority group, are included in the Screened Chemicals List (SCL).

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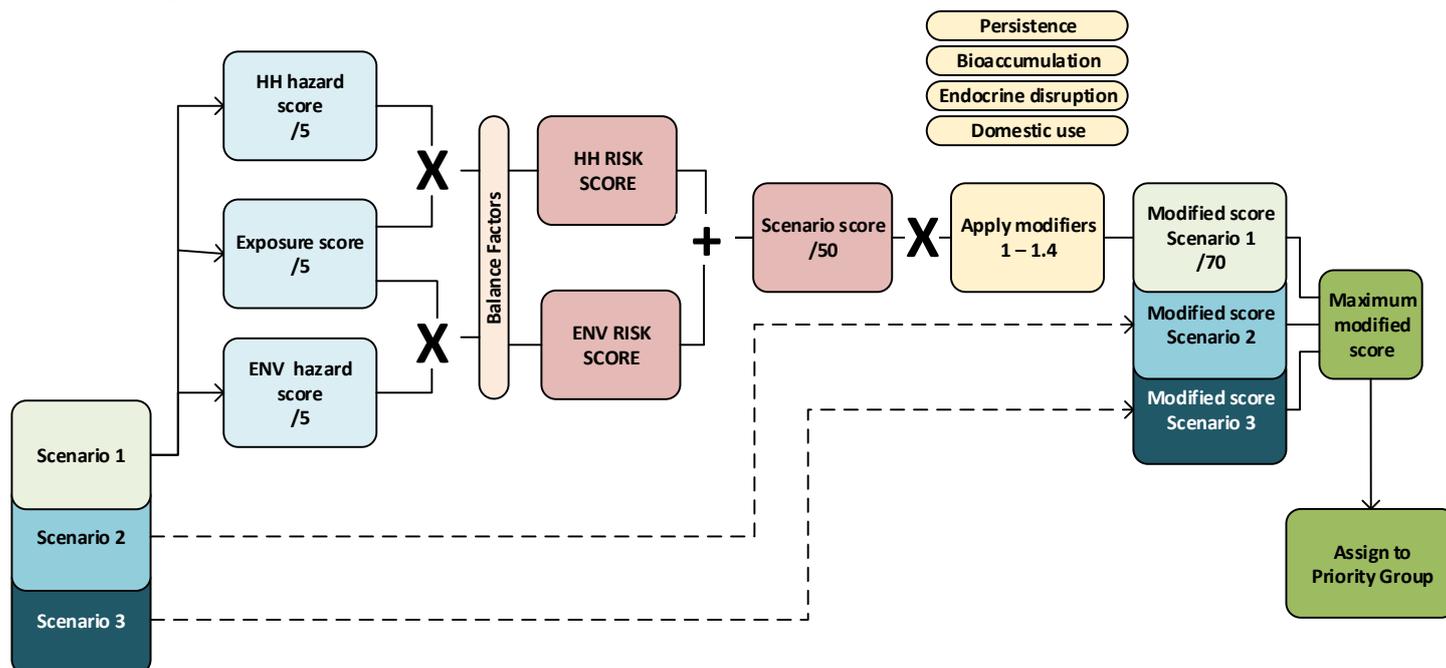
<sup>1</sup> As detailed in the Novachem New Zealand Agrichemical Manual 2016/17.

## 6. How FRCaST works

6.1. The purpose of FRCaST is to provide a representative score for a chemical, to determine which chemicals of interest should be considered a risk-based priority and to inform the reassessment work plan.

6.2. Figure 2 provides an overview of the screening process. Please note that the expanded process shown for Scenario 1 is equally applicable to the other scenarios, but has been omitted in the interest of clarity.

**Figure 2. The FRCaST screening process**



6.3. For each chemical of interest, the different ways it is used in New Zealand are identified and aligned with a range of use scenarios.

6.4. For each scenario, exposure factors are determined for human health and the environment.

6.5. The appropriate scenario balance factor are identified. These are a measure of how weighted towards human health risk or environmental health risk a particular scenario is.

6.6. The Human Health Hazard Factor, Exposure Factor and appropriate scenario Balance Factor are multiplied together to produce the Human Health Risk Score. Similarly, the Environmental Hazard Factor, Exposure Factor and appropriate Balance Factor are multiplied together to produce the Environmental Risk Score.

6.7. The human health and environmental Risk Scores are added together to produce the Combined Scenario Score.

6.8. The Combined Scenario Score is then multiplied by the Modifier Multiplier to produce the Modified Scenario Score. The Modifier Multiplier is a value between 1.0 and 1.4 that takes into account the four key modifying properties: persistence, bioaccumulation, endocrine disruption, and use in and around the home.

6.9. The chemical is then assigned to one of six Priority Groups based on the worst-case scenario score; that is, the highest Modified Scenario Score.

## Developing use scenarios

6.10. Twenty-six standard use scenarios (such as commercial use, home use, timber treatment, veterinary medicines) are present in FRCaST, representing different uses of a chemical. Comparing individual use scenarios allows a composite picture of the potential risk to be developed for each chemical. These use scenarios are broadly grouped into two bands, based on the expected exposures to non-professional and professional people:

- d) use within/around dwellings (including publicly accessible places)
- e) use in non-dwelling locations (including industrial and commercial settings).

6.11. Use information (such as how the substance is applied and intended use purpose) are used as input values to define specific use scenarios. Data selection is important as the use scenarios need to be representative of how the chemical is used. Screening is an approximation and does not represent a comprehensive risk assessment.

6.12. For each use scenario, an estimate is made about exposure associated with those particular uses. The exposure category represents a level of dispersion or containment but does not factor specific use parameters (such as application rates and frequencies).

6.13. Information on how a substance is used may come from a number of sources, including:

- a) EPA's internal database
- b) approval documentation for the hazardous substances
- c) product labels and other public domain use information (eg Ministry of Primary Industries' Agricultural Compounds and Veterinary Medicines (ACVM) public register<sup>2</sup>, manufacturer website, and product information)
- d) for those substances deemed approved through group standards especially, information was gathered from other sources, including from other international regulators such as Australia's NICNAS and the European Chemical Agency (ECHA).

## Screening assessment

6.14. The screening assessment makes an estimation of risk, and this determines a score (ie a number of points) based on the effect and likelihood of exposure. An indication of chemical risk is qualitatively determined by multiplying scores for hazard and exposure.

6.15. The approach taken is to generate a Scenario Risk Score ( $S_R$ ) for each scenario. This is based on simply adding together Human Health Risk Score ( $S_{HH}$ ) and the Environmental Risk Score ( $S_E$ ).

$$S_R = S_{HH} + S_E$$

6.16. Both of these constituent scores;  $S$ , is the result of multiplying three corresponding factors: the Hazard Factor,  $H$ , the Exposure Factor,  $E$ , and the Balance Factor,  $BF$ .

$$S_{HH} = H_{HH} \times E \times BF_{HH}$$

$$S_E = H_E \times E \times BF_E$$

$$S_R = (H_{HH} \times E \times BF_{HH}) + (H_E \times E \times BF_E)$$

6.17. A description of how these factors are determined follows.

<sup>2</sup> <https://eatsafe.nzfsa.govt.nz/web/public/acvm-register>

### Human Health Hazard Factor ( $H_{HH}$ )

6.18. The determination of Human Health Hazard Factor ( $H_{HH}$ ) is based on the hazard classification<sup>3</sup> of the chemical in question. The HSNO hazard classifications for human health have been assigned one of four hazard categories based on their severity. These categories align with those used by group standards as the primary hazards or subsidiary hazards, with those hazards related to carcinogens, mutagens and reproductive toxicants as well as acute toxicity at low doses elevated to the highest hazard category. Each of these categories is assigned a score as described in Table 1.

**Table 1. Human health hazard classification categories and associated scoring values**

HSNO classification	Human Health Hazard Category	Human Health Hazard Factor ( $H_{HH}$ )
6.1A 6.6A, 6.6B, 6.7A, 6.7B 6.8A, 6.8B	1	5
8.2A 8.3A 6.5A 6.9A	2	3
8.2B, 8.2C 6.1B, 6.1C 6.5B 6.9B	3	2
6.1D, 6.1E 6.3A, 6.3B 6.4A	4	1

6.19. Scoring for the human health hazards of a chemical is hierarchical.

- If a chemical has any category 1 hazards, a Hazard Factor of 5 is assigned. No further hazard classifications are taken into account.
- If a chemical has no category 1 hazards, and has any category 2 hazards, a Hazard Factor of 3 is assigned. No further hazard classifications are taken into account.
- If a chemical has no category 1 or 2 hazards, and has any category 3 hazards, a Hazard Factor of 2 is assigned. No further hazard classifications are taken into account.
- If a chemical has no category 1, 2 or 3 hazards, and has any category 4 hazards, a Hazard Factor of 1 is assigned.

<sup>3</sup> Determined from the formal HSNO classification of the substance, taking into account other information such as from NICNAS and ECHA as appropriate.

### Environmental Hazard Factor ( $H_E$ )

6.20. A different approach is taken for determining the Environmental Hazard Factor ( $H_E$ ), which is based on the number of 9.xA and 9.xB classifications (ie 9.1A, 9.1B, 9.2A, 9.2B, 9.3A, 9.3B, 9.4A and 9.4B). The ecotoxicity values associated with each classification are used to determine the Environmental Hazard Factor, in a similar manner to determination of ecotoxicity multiplying (M) factor values.<sup>4</sup> Both acute and chronic ecotoxicity values are considered in determining the Environmental Hazard Factor. Chronic adverse effects tend to result from lower exposures than acute effects and so the corresponding hazard factor thresholds for chronic toxicity are set to be an order of magnitude lower than for acute toxicities.

6.21. A chemical's Environmental Hazard Factor ( $H_E$ ) is determined by calculating an environmental hazard factor for each of the ecotoxicity classifications and selecting the highest individual hazard factor as the Environmental Hazard Factor ( $H_E$ ) for the chemical. The individual environmental hazard factors are determined in accordance with Table 2.

**Table 2. Conversion of classifications and ecotoxicity values to an environmental hazard factor**

HSNO subclass		Acute toxicity value	Chronic toxicity value	Equivalent M-factor	Hazard factor
Aquatic toxicity	9.1A	< 0.001 mg/L	< 0.0001 mg/L	1,000; 10,000	5
		> 0.01 to ≤ 0.001 mg/L	> 0.001 to ≤ 0.0001 mg/L	100	4
		> 0.01 to ≤ 0.1 mg/L	> 0.001 to ≤ 0.01 mg/L	10	3
		>0.1	>0.01	1	2
	9.1B	-	-	-	1
Terrestrial toxicity	9.2A	< 0.001 mg/L	< 0.0001 mg/L	1,000; 10,000	5
		> 0.01 to ≤ 0.001 mg/L	> 0.001 to ≤ 0.0001 mg/L	100	4
		> 0.01 to ≤ 0.1 mg/L	> 0.001 to ≤ 0.01 mg/L	10	3
		>0.1	>0.01	1	2
	9.2B	-	-	-	1
Toxicity to terrestrial vertebrates	9.3A	< 0.05 mg/L (oral/dermal) < 0.5 ppm (diet)	< 0.005 mg/L (oral/dermal) < 0.05 ppm (diet)	1,000; 10,000	5
		> 0.05 to ≤ 0.5 mg/L (oral/dermal) > 0.5 to ≤ 5 ppm (diet)	> 0.005 to ≤ 0.05 mg/L (oral/dermal) > 0.05 to ≤ 0.5 ppm (diet)	100	4
		> 0.5 to ≤ 5 mg/L (oral/dermal) > 5 to ≤ 50 ppm (diet)	> 0.5 to ≤ 5 mg/L (oral/dermal) > 0.5 to ≤ 5 ppm (diet)	10	3

<sup>4</sup> M factors are an indication of the potency of ecotoxic substances, used in mixture rules calculations to differentiate between the potency of a chemical within the most toxic classification category (9.xA): a more ecotoxic substance has a higher M factor than another chemical if its toxicity is an order of magnitude greater. See 'Assigning a Product to a HSNO Approval' for more details.

HSNO subclass		Acute toxicity value	Chronic toxicity value	Equivalent M-factor	Hazard factor
		> 5 mg/L (oral/dermal) > 50 ppm (diet)	> 5 mg/L (oral/dermal) > 5 ppm (diet)	1	2
	9.3B	-	-	-	1
Toxicity to terrestrial invertebrates	9.4A	< 0.002 µg/terrestrial invertebrate	< 0.0002 µg/terrestrial invertebrate	1,000; 10,000	5
		> 0.02 to ≤ 0.002 µg/terrestrial invertebrate	> 0.002 to ≤ 0.0002 µg/terrestrial invertebrate	100	4
		> 0.2 to ≤ 0.02 µg/terrestrial invertebrate	> 0.02 to ≤ 0.002 µg/terrestrial invertebrate	10	3
		> 0.2 µg/terrestrial invertebrate	> 0.02 µg/terrestrial invertebrate	1	2
	9.4B	-	-	-	1

### Exposure Factor (E)

6.22. The Exposure Factor is the other key qualitative parameter necessary to estimate risk. The Exposure Factor is an indication of the level of exposure that a particular use scenario presents to the various receptors.

6.23. The Exposure Factor is a qualitatively derived value between 0 and 5, intended to reflect the level of exposure associated with particular use patterns. This approach of using a use category as an indication of exposure is common to many prioritisation schemes from other jurisdictions (eg NICNAS's IMAP programme<sup>5</sup> and USEPA's Toxic Substances Control Act (TSCA) prioritisation<sup>6</sup>).

6.24. Sources of use information include the EPA's internal database, ACVM register, product information and labels, as well as available resources from overseas (such as NICNAS's database<sup>7</sup>, ECHA's chemical information<sup>8</sup> and the Canadian Domestic Substances List categorisation<sup>9</sup>).

The specific qualitative descriptors for each exposure level describe the level of containment and exposure associated with that use. While the specific descriptions will vary with use scenario, in general, the higher the level of exposure and lower the level of containment, the higher the exposure factor. Each use scenario is assigned an exposure factor that reflects the degree to which the chemical is contained or dispersed (ie 'available' for exposure) and incorporates some consideration of the degree of exposure to non-professionals and bystanders. The Exposure Factor description is intended to align with international approaches where appropriate (eg use of a chemical in cosmetic products is designated as the highest exposure factor). Although not definitive, the exposure descriptions are provided in

6.25. Table 3, with some examples, and give a general indication of the increase of Exposure Factor in different scenarios.

<sup>5</sup> <https://www.nicnas.gov.au/chemical-information/imap-assessments>

<sup>6</sup> <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemicals>

<sup>7</sup> <https://www.nicnas.gov.au/>

<sup>8</sup> <https://echa.europa.eu/search-for-chemicals>

<sup>9</sup> <https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/substances-list/domestic/categorization-existing.html>

**Table 3. Indicative descriptions of Exposure Factors**

Exposure Factor	Description	Example use scenarios
1	Entirely contained	No likelihood of release; chemical is entirely contained Use of substance in manufactured articles
2	Contained delivery (/ use)	Commercial use of pesticides via point-source release (eg food troughs) or bait stations Non-dispersive uses of industrial chemicals (eg in enclosed manufacturing processes, use in closed systems)
3	Minimal dispersion (/ exposure)	Commercial use of pesticides via hand-held spray application or hand-held distribution Commercial/professional use of indoor, small-scale pesticide sprays (eg aerosol fly sprays) Chemical irrigation Spot-on veterinary medicine uses by non-professionals
4	Dispersive (/ moderate exposure)	Commercial use of pesticides via outdoor granule or solid application, or by powered backpacks Dispersive use of veterinary medicines (eg dips, spray-frame, jetting) Indoor fumigations Domestic use pesticides - contained delivery Use of VTAs in domestic settings via bait-stations
5	Highly dispersive (/ high exposure)	Commercial use of pesticides via aerial or outdoor ground-based spraying (ie wide-dispersive) Outdoor fumigation applications Domestic use pesticides – sprayed indoor, outdoor Use of VTAs in domestic settings (not using bait-stations) Cosmetic products Uncontained use of chemicals in consumer products (eg cleaning products, laundry products, paints) Dispersive uses (ie releases to environment/atmosphere anticipated) of industrial chemicals

6.26. It is worth noting that domestic use of sprayed chemicals is designated as the highest exposure factor, on the assumption that protective equipment is not used by domestic users, and that domestic users cannot be expected to have comprehensive knowledge or expertise in handling hazardous substances. A degree of extra conservatism has been assigned to domestic use scenarios in general.

### Balance Factors (BF)

6.27. Balance Factors (BF) were introduced in FRCaST to account for the fact that, in certain scenarios, one element of the hazard (either human health or environmental) might be more relevant. For example; for the scenario of use as part of a cosmetic product, the human health risk will be of more concern than the associated environmental risk. These balance factors are a set of two factors ( $BF_{HH}$  and  $BF_E$ ) per scenario; one applied to the human health side of the equation, and one applied to the environmental side. The sum of the two factors for a given scenario is always equal to 2 (ie if one of the factors is above 1 then the other will be less than 1 by the same amount). Table 4 details the different balance factors that apply for a given scenario.

**Table 4. Balance Factors for individual scenarios**

Scenario		Human Health Balance Factor	Environmental Balance Factor
Within/around dwellings	Cosmetic product	1.2	0.8
	Household cleaner	1.2	0.8
	Other household use	1.2	0.8
	Pesticide – non-professional – aquatic	1	1
	Pesticide – non-professional – indoor	1.2	0.8
	Pesticide – non-professional – outdoor	1	1
	Pesticide – professional – aquatic	1	1
	Pesticide – professional – indoor	1.2	0.8
	Pesticide – professional – outdoor	1	1
	VTA – non-professional	1	1
	VTA – professional – non-bait station (ie dispersive)	1	1
	VTA – professional – bait station	2	0
	Non-dwelling related	Fumigation – indoor	1
Fumigation – outdoor		1	1
Industrial		1	1
Pesticide – commercial – aerial		1	1
Pesticide – commercial – aquatic		1	1
Pesticide – commercial – aquatic aerial		1	1
Pesticide – commercial – indoor		1	1
Pesticide – commercial – outdoor		1	1
Seed treatment		1	1
Timber treatment		1	1
Veterinary Medicine		1	1
VTA – non-bait station (ie dispersive)		1	1
VTA – bait station		2	0

### Component Risk Scores ( $S_{HH}$ and $S_E$ )

6.28. The component Risk Scores,  $S_{HH}$  and  $S_E$ , are the products of multiplying the relevant Hazard Factors, Exposure Factor and Balance Factors:

$$S_{HH} = H_{HH} \times E \times BF_{HH}$$

$$S_E = H_E \times E \times BF_E$$

### Scenario Risk Score ( $S_R$ )

6.29. The Scenario Risk Score ( $S_R$ ) is the combined score of the Human Health Risk Score ( $S_{HH}$ ) and the Environmental Risk Score ( $S_E$ ) for a given use scenario.

$$S_R = S_{HH} + S_E$$

6.30. The maximum Scenario Risk Score is 50. As described in following sections, this score may be subject to further modification and weighting.

### Modification of risk scores

6.31. Four key modifiers have been included to augment the raw scores in order to give greater weighting to those chemicals that have been identified as presenting certain issues of high concern.

6.32. In line with approaches taken overseas, bioaccumulation, persistence and endocrine disruption are key properties that are specifically taken into account and considered to be modifiers in FRCaST. The domestic use of chemicals is also considered a modifier to account for the chemicals' close proximity to the general public.

6.33. This approach allows the differentiation of chemicals that present similar risk scores, based on a number of properties of high concern.

6.34. The Modifier Multiplier (MM) is calculated so;

$$MM = 1 + (0.1 \text{ for each modifying criteria present})$$

6.35. As such, for each modifier identified for a chemical, the unmodified scenario score is increased by 10%. The Modifier Multiplier is applied as a factor to the Scenario Risk Scores to generate the Modified Scenario Risk Score.

6.36. For example, the scenario score for a substance that presents two of the key issues of concern is increased by 20% (ie the unmodified Scenario Risk Score is multiplied by a Modifier Multiplier of 1.2)

6.37. FRCaST has the option of incorporating further modifier properties, such as persistent organic pollutant (POP) status, volatility and groundwater effects. These additional modifiers, however, are not in use at this time.

### Further potential weightings of scores

#### Prevalence

6.38. Currently, FRCaST treats all use scenarios as equivalent. In reality, certain uses may be more prevalent than others. If this information is available, it could be provided to refine and scale the respective use scenarios. This weighting factor is called 'Prevalence'.

6.39. Prevalence has not been included in the screening process so far and so each use scenario has been treated equally. Refinement may be possible by applying weighting to each scenario, based on its contribution to overall use of the substance should this information become available in the future.

6.40. Further information may be requested post-screening, for candidates that are being considered for inclusion on the Reassessment Work Plan.

### Significance

6.41. Currently, FRCaST does not take into account volumes of use in NZ. Use-volume data, if available, can be used after initial screening to modify the screening score to take this into account and provide an indication of the significance of the risks presented by all uses of the chemical. This weighting factor is called 'Significance'.

6.42. Significance is not part of the screening at this time. It may be considered as part of subsequent decisions on reassessment candidates to be added to the work-plan.

6.43. 'Prevalence' applies to use scenarios for a chemical affecting the scenarios scores; whereas 'Significance' applies to the overall score for a chemical, affecting where a chemical lies relative to other chemicals.

### Priority Groups

6.44. The results from the FRCaST screening are assigned to a number of Priority Groups (A through F), based on the highest, modified score for an individual scenario for a chemical.

6.45. We considered three values that may be useful for the purposes of categorisation:

- a) Total risk: if the total risk for all scenarios is used to categorise chemicals, then there will be a prioritisation bias towards substances with higher numbers of use scenarios.
- b) Maximum Scenario Risk Score: if chemicals are categorised using the highest individual Scenario Risk Score then it will be the highest risk use that drives the categorisation (ie based on worst-case scenario). There will be no distinction between chemicals that have scores in a number of use scenarios, versus chemicals that score only in a single use scenario. One reason for using the maximum Scenario Risk Score rather than the total score is to ensure that the number of use scenarios is not the determining factor in prioritisation. However, use of the maximum Scenario Risk Score gives no indication of the risks presented by other use scenarios that present lower risks.
- c) Average Scenario Risk Score: if chemicals are categorised using the average Scenario Risk Score, then the highest risk scenarios will not necessarily be identified, nor the spread of risks across different use scenarios.

6.46. The Maximum Modified Scenario Risk Score (b. from above) has been chosen to determine a Priority Group as this represents the worst-case scenario for a chemical.

6.47. At the end of the screening process, Priority Group categorisation is based on where the thresholds between the groups have been set. These thresholds are arbitrarily set at 10 and multiples thereof to give the seven priority groups. The term Priority Group has been reserved for categorising the Maximum Modified Scenario Risk Scores.

6.48. FRCaST also calculates other risk scores which can be used to categorise on the combination of use around dwellings/non-dwelling locations and the associated human health/environmental risks, resulting in four segments. The distribution of these risk scores for different might be used for further analysis or prioritisation in the future. More information on these segments can be found in the accompanying 'FRCaST-operating instructions' document.

## 7. Further work

### Additional screening input streams

- 7.1. Future revisions of FRCaST might accommodate input data from different kinds of sources, including:
- a) a scoring method intended to use the outcomes of overseas regulators as the basis for categorisation
  - b) a scoring system that will allow issues that may not be related to a single chemical, such as those associated with a particular type of pesticide or application method, to be considered
  - c) information regarding use volumes in New Zealand and application rates
  - d) new modifiers and weightings such as 'prevalence' and 'significance'.

### Refinement of prioritisation

- 7.2. Further work might consider if changes to the process could yield a more accurate description of the risk posed by individual chemicals, such as:
- a) weighting of various factors (such as exposure scores) slightly differently
  - b) different approach to using the various scenario Risk Scores to categorise overall risk.

## 8. Summary

8.1. This screening tool is intended to provide an indication of risk to inform decisions when developing the EPA's reassessment programme and work-plan. FRCaST makes a number of assumptions in order to undertake this screening.

8.2. FRCaST is a qualitative screening tool that considers different receptor groups. Chemicals are screened based on a use scenario that best represents how the substance is used. This should not be interpreted to represent the complete range of uses of the substance, rather provides an initial indication of the approximate level of risk presented. With additional information, refinement would be possible if different use parameters are more appropriate.

8.3. Scores have been determined based on risk (comprised from effects and likelihood). Scores are further modified based on a number of key properties of the chemical.

8.4. Use information has been sourced from a range of publicly available resources, and considers known New Zealand uses and those specified internationally.

8.5. Chemicals assigned to Priority Groups A and B form the Priority Chemicals List (PCL).

8.6. This list will form the basis of the EPA's reassessments work plan.

8.7. When developing the work-plan the EPA will further consider the relevance to New Zealand and whether a reassessment is the most appropriate route to deal with the potential risks identified. Although volumes of chemicals in or used in New Zealand are not included in the screening process, where such data is available the EPA will use its discretion as to whether incorporate them as a 'New Zealand lens' to assess whether the chemical poses a serious concern to New Zealand.

8.8. FRCaST has been peer-reviewed by two overseas regulators to ensure that the approach is fit for purpose and aligns with international best practice. Input data and screening results have been subjected to internal quality control to ensure that FRCaST has been used consistently.

8.9. FRCaST might be modified in the future to allow different inputs and changes to the calculations if it were deemed that, in doing so, it would result in a more accurate representation of the risks.

## Appendix 1 - List of resources used to develop initial Chemicals of Interest list

### New Zealand CEIR list

The Environmental Protection Authority, *Chief Executive-initiated Reassessments: CEIR list*  
<http://www.epa.govt.nz/hazardous-substances/reassessments-reviews/Pages/Chief%20Executive%20Initiated%20Reassessment%20list.aspx> Retrieved 20 July 2016

### Norway priority substances

The Norwegian Environment Agency, 2015. *List of Priority Substances*.  
<http://www.environment.no/topics/hazardous-chemicals/lists-of-hazardous-substances/list-of-priority-substances/> Retrieved 20 July 2016

### Europe

European Chemicals Agency (ECHA), 2016. *Authorisation List*. <http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list> Retrieved 20 July 2016

European Chemicals Agency (ECHA), 2016. *Candidate List of substances of very high concern for Authorisation*. <http://echa.europa.eu/candidate-list-table> Retrieved 20 July 2016

European Chemicals Agency (ECHA), 2016. *Substances restricted under REACH*.  
<http://echa.europa.eu/addressing-chemicals-of-concern/restrictions/substances-restricted-under-reach>  
Retrieved 20 July 2016

European Commission, 2015. *DRAFT List of candidates for substitution (January 2015)*.  
[http://ec.europa.eu/food/plant/pesticides/approval\\_active\\_substances/docs/draft\\_list\\_cfs\\_en.pdf](http://ec.europa.eu/food/plant/pesticides/approval_active_substances/docs/draft_list_cfs_en.pdf) Retrieved 20 July 2016

### Australia

National Industrial Chemicals Notification and Assessment Scheme (NICNAS), 2015. *Priority Existing Chemical (PEC) Assessments*. <https://www.nicnas.gov.au/chemical-information/pec-assessments> Retrieved 20 July 2016

Australian Pesticides and Veterinary Medicines Authority, 2016. *Chemicals nominated and prioritised for reconsideration*. <http://apvma.gov.au/node/10876> Retrieved 20 July 2016

### USA

US Environmental Protection Agency, 2016. *Current Chemical Risk Reduction Activities*.  
<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-reduction-activities> Retrieved 20 July 2016

US Environmental Protection Agency, 2014. *TSCA Work Plan for Chemicals Assessments: 2014 Update*.  
[https://www.epa.gov/sites/production/files/2016-02/documents/tsca\\_work\\_plan\\_2014\\_update\\_tables.pdf](https://www.epa.gov/sites/production/files/2016-02/documents/tsca_work_plan_2014_update_tables.pdf)  
Retrieved 20 July 2016

## Canada

Environment and Climate Change Canada, 2013. *First Priority Substances List (PSL1)*  
<http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=95D719C5-1> Retrieved 20 July 2016

Environment and Climate Change Canada, 2013. *Second Priority Substances List (PSL2)*  
<http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=C04CA116-1> Retrieved 20 July 2016