

# FRCaST peer review summary

1. The EPA has sought feedback on its FRCaST (Flexible Reassessment Categorisation Screening Tool) approach to prioritisation of chemicals for reassessment. This exercise was considered essential to ensure that we are able align our approach with what is considered best practice internationally. A number of modifications to how FRCaST works have been implemented.

## Peer review of screening approach by overseas regulators/experts

2. The National Industrial Chemicals Notifications and Assessment Scheme (NICNAS) in Australia and Health Canada (HC) / Environment and Climate Change Canada (ECCC) agreed to undertake a review of our screening and categorisation approach.
3. On 26 February 2018, these agencies were provided with a package of documents related to the approach to screening and the screening tool, FRCaST.
4. The aim of the peer review was to ensure that our approach to screening is fit-for-purpose, defensible and capable of producing reliable screening outputs that will inform the Reassessment Work Plan.
5. The reviewers from NICNAS and HC/ECCC provided their feedback in late April/early May 2018. Analysis of this feedback identified key points that are grouped under six main criteria, together with proposed actions to be taken to address any concerns or suggested improvements. This analysis is presented in Table 1.
6. 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.
7. There were some suggestions for adjustment to the hazard scoring system to better align with the approaches used in Australia, Canada, and other major international jurisdictions. These suggestions were considered and implemented where appropriate.
8. Other comments relate to limitations of the screening approach and to screening/prioritisation of chemicals in general.

**Table 1 Analysis of Feedback. Items marked with [\*] are considered to be globally relevant (ie not specific to New Zealand).**

Review criteria	Key points from NICNAS (Australia) feedback	Key points from Health Canada / Environment and Climate Change Canada feedback	EPA response
General comments	<ul style="list-style-type: none"> <li>• [*] Proposed screening approach is aligned with best practice by integrating exposure information at an early stage.</li> <li>• Proposed screening approach is fairly complex / may be difficult to communicate to stakeholders.</li> <li>• The approach doesn't distinguish between existing hazards / exposures and new information on hazards / exposures.</li> </ul>	<ul style="list-style-type: none"> <li>• The approach is transparent and reproducible.</li> <li>• Generally, the scheme is practical and fit-for-purpose.</li> <li>• [*] Key limitation appears to be how to handle uncertainties around particular criteria.</li> <li>• Consider using the 4,300 chemicals identified under Canada's Chemical Management Plan (CMP) as a screening input</li> <li>• Consider using the prioritised chemicals as a high hazard list, or mechanism for promoting alternative chemistries.</li> </ul>	<ul style="list-style-type: none"> <li>• Simplified screening approach where possible when making any revisions.</li> <li>• Ensured documentation describes data sources used for identifying hazards / exposures.</li> </ul>
Appropriateness of hazard scoring process	<ul style="list-style-type: none"> <li>• Consider grouping chemicals within the screening stage</li> <li>• Suggestions for improvement of the scoring system:               <ul style="list-style-type: none"> <li>○ [*] Separation of CMR chemicals into a higher scoring category</li> <li>○ Splitting of differing levels of acute toxicity, skin corrosion, and sensitisation hazards across scoring categories.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• [*] Uncertainty around how screening accounts for chemicals with no information available on particular hazardous property endpoints.</li> <li>• Uncertainty around whether both chronic and acute ecotoxicity hazards are considered</li> <li>• [*] Suggestion to give a higher score or additional modifier to CMR chemicals</li> </ul>	<ul style="list-style-type: none"> <li>• Ensured documentation acknowledges limitations of screening for "data-poor" chemicals.</li> <li>• Modified scoring system to include additional higher tier for CMR chemicals (known and suspected)</li> <li>• Modified scoring system to differentiate levels of acute toxicity, skin corrosion, and sensitisation hazards</li> <li>• Included chronic ecotoxicity scoring.</li> </ul>

Review criteria	Key points from NICNAS (Australia) feedback	Key points from Health Canada / Environment and Climate Change Canada feedback	EPA response
Appropriateness of exposure scoring process and scenario selection	<ul style="list-style-type: none"> <li>Consider having separate scores for human health and environment.</li> </ul>	<ul style="list-style-type: none"> <li>Suggest separating scores for human health and environment aspects.</li> </ul>	<ul style="list-style-type: none"> <li>Retained overall scoring system, but modify output to allow human health and environment scores to be displayed separately.</li> </ul>
Appropriateness of weighting between human health and environmental components of risk score	<ul style="list-style-type: none"> <li>Consider revising the weighting between human health and environmental components for indoor use of chemicals to take into account release to the environment through waste water.</li> </ul>	<ul style="list-style-type: none"> <li>Indoor use of household chemicals needs to take into account releases to the environment (eg through waste water). This would require revising the balance between human health and environmental components for domestic indoor use of chemicals.</li> </ul>	<ul style="list-style-type: none"> <li>Modified weighting for indoor use of household chemicals scenarios to a 60:40 ratio between human health and environmental components to factor in waste water release to the environment.</li> </ul>
Appropriateness of modifying criteria	<ul style="list-style-type: none"> <li>[*] Key limitation appears to be uncertainty around criteria for endocrine disrupting chemicals (EDCs)</li> <li>Uncertainty around the reason for including persistence / bioaccumulation as a modifier rather than integrating into the hazard scoring.</li> </ul>	<ul style="list-style-type: none"> <li>Queries around the domestic use modifier – use in New Zealand vs household use and possible double-counting.</li> <li>[*] Identified uncertainty regarding criteria for endocrine disrupting chemicals (EDCs), and unknown EDC properties for many chemicals, plus possible double-counting where toxicity hazard is related to EDC properties.</li> <li>Suggestion to include mobility (M) and long-range transport (LRTP) as additional modifiers</li> </ul>	<ul style="list-style-type: none"> <li>Changed terminology to ‘household use’, and ensure documentation clearly describes reasons for additional weighting.</li> <li>Retained modifier for endocrine disrupting chemicals; added acknowledgement in documentation around uncertainties in EDC testing criteria and amount of test data available.</li> <li>Retained persistence / bioaccumulation modifier.</li> <li>Additional modifiers could be considered in future, but insufficient data available for current screening.</li> </ul>
Categorisation of screened chemicals	<ul style="list-style-type: none"> <li>Use of maximum modified scenario score to drive categorisation is consistent with NICNAS IMAP Scheme approach.</li> </ul>	<ul style="list-style-type: none"> <li>The most appropriate metric to prioritise chemicals seems to be the maximum modified scenario score, but may favour chemicals with anticipated dispersive uses.</li> </ul>	<ul style="list-style-type: none"> <li>No action required</li> </ul>

## Refinement of the screening tool

9. The main adjustment suggested for human health hazard scoring was to separate chemicals with carcinogenic, mutagenic or reproductive toxicity (CMR) properties into a higher tier hazard score, together with extremely acutely toxic chemicals, and to score both known and suspected CMR chemicals equally highly. The single highest scoring hazard now directly equates to a human health hazard score, rather than using a cumulative scoring system for multiple hazards. These changes have been implemented in the modified scoring system within FRCaST.
10. Other minor changes to the hazard scoring categories were to differentiate the levels of acute toxicity and skin corrosion/irritation into separate categories, and to differentiate the scoring for contact and respiratory sensitisation hazards.
11. The adjusted human health hazard scoring system is shown in Table 2.

**Table 2 New human health scoring system**

Human Health Hazard Factor (H <sub>HH</sub> )	Revised criteria	Original criteria
5	Any of: 6.1A 6.6A, 6.6B, 6.7A, 6.7B 6.8A, 6.8B	3 classifications from: 6.1A-C, 6.6A, 6.7A, 6.8A, 6.8C, 6.9A, 8.2A-C
4	(not used)	2 classifications from: 6.1A-C, 6.6A, 6.7A, 6.8A, 6.8C, 6.9A, 8.2A-C
3	If no higher classification, any of: 8.2A 8.3A 6.5A 6.9A	1 classifications from: 6.1A-C, 6.6A, 6.7A, 6.8A, 6.8C, 6.9A, 8.2A-C; or 3 classifications from: 6.1D, 6.5A-B, 6.6B, 6.7B, 6.8B, 6.9B, 8.3A
2	If no higher classification, any of: 8.2B, 8.2C 6.1B, 6.1C 6.5B 6.9B	1 or 2 classifications from: 6.1D, 6.5A-B, 6.6B, 6.7B, 6.8B, 6.9B, 8.3A
1	If no higher classification, any of: 6.1D, 6.1E 6.3A, 6.3B 6.4A	1 to 3 classifications from: 6.1E, 6.3, 6.4

12. The only adjustment suggested for environment hazard scoring was to include scoring for chronic ecotoxicity endpoints as an alternative to the acute ecotoxicity endpoint. It seems appropriate that

both acute and chronic endpoints are considered for environmental risk, with the highest scoring risk driving the score, as this is consistent with the approach for the human health risk.

13. One reviewer noted that the screening approach is fairly complex and may be difficult to communicate to stakeholders. While revising the scoring system, the screening tool has been simplified where possible to improve efficiency and ease of use, as well as allowing for ease of communication with stakeholders. For example, while making the adjustment to factor in the chronic ecotoxicity endpoints, the screening tool was simplified so that ecotoxicity data are now entered into the tool directly and used to determine the environmental hazard factor, rather than performing a manual calculation of multiplication factors (M-factors) for each chemical. This automated approach avoids the possibility of miscalculation errors.
14. The Flexible Reassessment Categorisation Screening Tool (FRCaST) support notes have been updated to reflect the refinements to the screening tool and the adjusted hazard scoring criteria