



Continual Improvement Technical Challenge Process v 2.0

2024\_02



Continual Improvement Technical Challenge Process v2.0

## Overview

ChemFORWARD seeks to ensure the publication of robust, comprehensive, and credible chemical hazard assessments (CHAs) by engaging qualified toxicologists, "Assessors" to produce CHAs which are subsequently peer reviewed by toxicology experts, "Verifiers." The Verification process is intended to ensure that the CHAs are comprehensive, consistent, and complete, that they are based on best practices in toxicology, and that they reflect a commitment to the protection of human health and the environment; see more information regarding verification in the document, "ChemFORWARD Verification Program," under "Our Approach" on the ChemFORWARD website <u>HERE</u>.

As is common with interpretation of toxicological data, there may be discrepancies in judgment as to what the most appropriate endpoint classifications are. These differences typically result from 1) reliance on different data or 2) differences in data interpretation. ChemFORWARD has set up a process for continual improvement that allows for technical challenges to hazard endpoint classifications or other chemical properties. The Continual Improvement Technical Challenge (Challenge) process is intended to accommodate new information and new data that were not available at the time of the initial assessment such as information in articles that were not yet published or internal data, i.e. data that were generated by private organizations and not publicly available. Internal data from private organizations will be viewed by both the Assessors and Verifiers, which can be conducted under NDA, if necessary. Results may be included in the data summary (not visible to users) in accordance with ChemFORWARD policy, for more information see the document titled "Policy on Use of Private Data" under "Our Approach" on the ChemFORWARD website HERE ".

Anyone who seeks to challenge any aspect of a CHA must fully document the rationale for their challenge and provide justification along with supporting data. Results from challenges will be included in the CHA reports and will include both the final agreement and the dissenting perspective.

- 1. Any aspect of a ChemFORWARD CHA may be subject to a challenge.
- 2. Any ChemFORWARD user, Assessor, or NGO partner may submit a challenge and will be referred to as the "Challenger". ChemFORWARD is building a community of practice so that all will benefit from the results of continual improvement technical challenges.
- 3. The challenge must be submitted via the <u>ChemFORWARD Technical Challenge form</u>. The challenge must be well documented including a written rationale for the dissenting opinion and supporting data that will be provided to the Assessor and the Verifier. Challenges that are not well documented or justified will be rejected.
- 4. The challenge will be vetted by ChemFORWARD technical staff. If it is credible and well documented, it will be approved to continue along in the challenge process. If not, the



Challenger will be informed and invited to revise their challenge documentation. Challengers will receive a response within 30 days.

- 5. The Challenger will agree to pay ChemFORWARD to cover the costs of the challenge process, including the costs for the Assessor who did the original work to review additional data or information and, if determined to be necessary by ChemFORWARD, for a Verifier to complete the Verification process.
- 6. The Assessor will review the additional information, enter it in the CHA data summary as appropriate, and recommend any modifications to the hazard classification or other entries. Note that this work will be scoped with the Assessor and timelines to completion may vary; verification requires additional time.
  - a. Challenges that involve the submission of private data will be reviewed by a Verifier in accordance with the Policy on Use of Private Data" under "Our Approach" on the ChemFORWARD website <u>HERE</u>. If required, ChemFORWARD will facilitate the establishment of an appropriate NDA between the interested parties.
  - b. For challenges that result in changes to the hazard classification, a Verifier may be engaged at ChemFORWARD's discretion.
  - c. ChemFORWARD will share the results with the Challenger via email or via a virtual meeting.
  - d. The Challenger may request a facilitated discussion with ChemFORWARD technical experts and the Assessor. Challengers may enlist additional experts in facilitated discussions.
- 7. Appropriate modifications to the CHA results will be made once the challenge process, (and subsequent verification, if necessary), is complete.
- 8. A record of challenges, outcomes and dates will be maintained with each CHA.
- 9. Any endpoint may be challenged again if new information or data are provided.

## **Fee Structure**

Costs for continual improvement technical challenges will be paid by the party initiating the challenge. Costs may include:

- 1. Assessor fees to review additional data and to modify the CHA and Verifier fees if necessary. These fees will be based on an agreed upon hourly rate.
- 2. A nominal management fee for ChemFORWARD to manage the challenge process once the challenge has been accepted.
- 3. Reduced or waived fees may be negotiated at the discretion of ChemFORWARD, especially for NGO partners.