

Each of you is playing the role of the **Government Regulator**:

A **government regulator** makes decisions about implementing new regulatory strategies and accepting alternative testing models by evaluating data provided from research scientists. For this scenario, you are part of the INTERNATIONAL COUNCIL ON SKIN SAFETY whose job is to examine a new model to evaluate the toxicity of chemicals that could replace animal testing. You have been given the following data from In Vitro Inc, who developed the test and propose it as the new testing strategy for classification of compounds as skin irritants or safe for human use.

The Data:

In the study below, 4 chemicals were tested using the Human Cell Culture Skin Tox Test and compared to the established rabbit skin model and the human patch test (HPT). Each chemical was evaluated in 12 different trials. If more than $\frac{3}{4}$ of the trials showed toxicity, the chemical was classified as an IRRITANT and if $\frac{3}{4}$ of the trials did not show toxicity, the chemical was classified as a NON-IRRITANT. *For simplicity, the positive and negative controls are not included in the data, but showed the appropriate responses to validate each trial.*

| | TOXICOLOGY TEST | | |
|------------|--|-----------------------|--------------------------------------|
| | Rabbit Skin Test | Human Skin Test (HP4) | In VITRO INC Human Cell Culture Test |
| | TEST RESULTS <i>(based on 12 different trials)</i> | | |
| Chemical A | IRRITANT | IRRITANT | NON-IRRITANT |
| Chemical B | IRRITANT | NON-IRRITANT | NON-IRRITANT |
| Chemical C | NON-IRRITANT | IRRITANT | IRRITANT |
| Chemical D | NON-IRRITANT | NON-IRRITANT | NON-IRRITANT |

Your Questions *(discuss as a group and be prepared to report out your key ideas)*

Question 1:

Discuss your interpretation of the variability within the data from the perspective of a government regulator. What general conclusions can you draw from the data?

Question 2:

As a government regulator, do you think a single method sufficient to determine toxicity of a compound? Why or why not? If not, how could we use a combination of tests to make regulatory decisions about chemicals?