



## Rethinking Carcinogenicity Assessment for Agrochemicals

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### INTRODUCTION

For the past 40 years, questions have been raised about the relevance and regulatory utility of rodent cancer bioassays in human health risk assessment. As a result, a working group of experts from different sectors has formed the Rethinking Carcinogenicity Assessment for Agrochemicals Project (ReCAAP) to determine the appropriateness of and criteria for waiving rodent cancer bioassays for the registration of food-use pesticides.

### METHODOLOGY

A reporting framework was developed using publicly available information to structure a weight of evidence (WoE) assessment to determine if sufficient information was available to perform a health-protective chronic risk assessment without conducting rodent cancer bioassays. Information used in the WoE includes exposure, mode-of-action, physiochemical properties, metabolism, and toxicological data from standard risk assessment endpoints.

### RESULTS

Using this framework, ReCAAP evaluated 15 pesticides registered over the past ten years with the chemical distribution spanning 10 tumour types, 15 chemical classes, and six cancer classifications (including subclasses). The reporting framework and example carcinogenicity waiver rationales will be presented.

### DISCUSSION

This effort has established a framework to support WoE assessment to identify when the mouse and/or rat cancer bioassay can be waived while ensuring that human health risk assessments are protective.