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REPORT CALLS FOR NEW DIRECTIONS, INNOVATIVE APPROACHES IN TESTING CHEMICALS FOR TOXICITY TO HUMANS

WASHINGTON -- Recent advances in systems biology, testing in cells and tissues, and related scientific fields offer the potential to fundamentally change the way chemicals are tested for risks they may pose to humans, says a new report from the National Research Council. The report outlines a new approach that would rely less heavily on animal studies and instead focus on in vitro methods that evaluate chemicals' effects on biological processes using cells, cell lines, or cellular components, preferably of human origin. The new approach would generate more-relevant data to evaluate risks people face, expand the number of chemicals that could be scrutinized, and reduce the time, money, and animals involved in testing, said the committee that wrote the report.

Today, researchers typically test the safety of commercial chemicals, pesticides, and other substances by administering large doses to groups of animals and observing them for symptoms of disease; these tests inform decisions about whether and how to regulate the chemicals' use. But how relevant the animal tests are for humans, usually exposed at much lower doses, has often been called into question. Moreover, the current approach is time-consuming and costly, resulting in an overburdened system that leaves many chemicals untested, despite potential human exposure to them, the report observes. Recognizing these limitations, the U.S. Environmental Protection Agency -- which oversees the testing of many agricultural, commercial, and industrial chemicals -- asked the Research Council to develop a new approach and strategy for toxicity testing.

The report recommends an approach that would take advantage of rapidly evolving scientific understanding of how genes, proteins, and small molecules interact to maintain normal cell function and how some of these interactions can be perturbed in ways that could lead to health problems. Specifically, the new testing approach would focus on toxicity pathways -- cellular pathways that, when sufficiently perturbed, are expected to lead to adverse health effects.

The committee recommends the use of "high-throughput assays" -- rapid, automated experiments that can test hundreds or thousands of chemicals over a wide range of concentrations -- to evaluate chemicals' effects on these toxicity pathways. On the basis of data from these and other experiments, researchers could develop models to describe responses in toxicity pathways, and other models to estimate the human exposure necessary to produce responses in these pathways.

Over time, the need for traditional animal testing could be greatly reduced, and possibly even eliminated someday, says the report. For the foreseeable future, however, targeted tests in

animals would need to be used to complement the in vitro tests, because current methods cannot yet adequately mirror the metabolism of a whole animal.

Studies observing human populations will be needed to provide information on human susceptibility and "background" exposures to chemicals that people face every day, so that results of the in vitro tests can be properly interpreted. These population studies may also reveal health risks not previously identified through toxicity testing. In addition, human exposure data can be used to select doses for toxicity testing, so that the tests generate information on biological effects at environmentally relevant exposures. By comparing human exposure data with concentrations that cause biologically significant alterations in toxicity pathways, researchers can identify potentially harmful exposures.

Current toxicity-testing practices are long established and deeply ingrained in some sectors, the report observes. But it emphasizes that the proposed changes will generate better data on the potential risks humans face from environmental agents, building a stronger scientific foundation that can improve regulatory decisions to mitigate those risks, and reducing the time, money, and animals needed for testing.

Implementing the strategy envisioned by the committee will require a substantial research effort to develop and validate all of the new approach's components, the report says. A critical factor for success is the creation of an institution that fosters multidisciplinary research. If the research is dispersed among different locations and organizations without a core organizing institute to enable communication and problem-solving across disciplines, there will be less chance of success within a reasonable time frame, the report says.

The study was sponsored by the U.S. Environmental Protection Agency. The National Academy of Sciences, National Academy of Engineering, Institute of Medicine, and National Research Council make up the National Academies. They are private, nonprofit institutions that provide science, technology, and health policy advice under a congressional charter. The Research Council is the principal operating agency of the National Academy of Sciences and the National Academy of Engineering. A committee roster follows.

Copies of TOXICITY TESTING IN THE TWENTY-FIRST CENTURY: A VISION AND A STRATEGY will be available from the National Academies Press; tel. 202-334-3313 or 1-800-624-6242 or on the Internet at HTTP://WWW.NAP.EDU. Reporters may obtain a pre-publication copy from the Office of News and Public Information (contacts listed above).