A Framework for Exposure-Based Assessments

VISION: Implementation of a globally harmonized risk assessment-based approach for regulatory decision-making of crop protection products.

Exposure-Driven Assessment of Crop Protection Chemicals through the Implementation of Risk-Based Approaches

This effort supports global, harmonized, risk assessment-based regulatory decision-making realized through the application of the best available science, via integration of new methods and traditional data to create tailored exposure-driven risk assessments. A globally harmonized risk assessment practice for agricultural chemicals achieved through an approach that emulates the goals of the International Conference of Harmonization (ICH) for pharmaceuticals [HYPERLINK "http://www.ich.org/home.html" \h]. The Crop Protection RoadMap, focusing on a regulatory outcome pathway that encourages direct communication between the regulatory community and the regulated industry will enable a more rapid incorporation of new technologies and advancing science. Implementation of this will increase the speed, efficiency and accuracy of regulatory decision-making for human health and environmental protection while increasing the efficiency of getting safe and effective innovative products into the hands of the growers.

Problem Statement:

Need a mechanism for food and agricultural chemistry industry and associated regulatory agencies to have a globally harmonized way to focus evaluation efforts on risk management to better support innovation.

Exploring the Problem:

Hazard only approach with questionable value of information that has focused only on hazard.

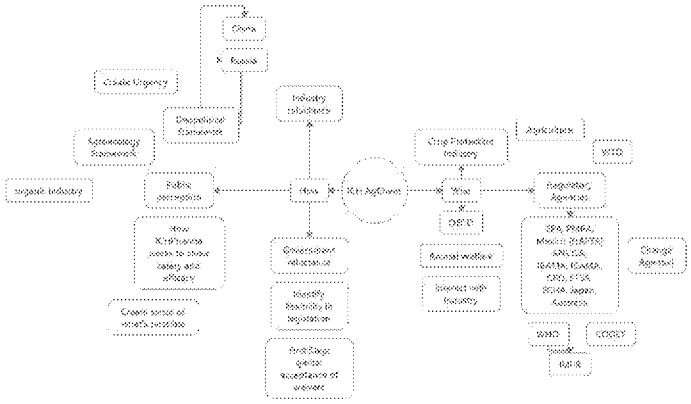
Lack of focus on risk with lack of benefit of current approach which becomes increasingly burdensome with no increase in health and environmental protection.

Is an innovation killer as there is a lack of focus on innovation rather than on testing?

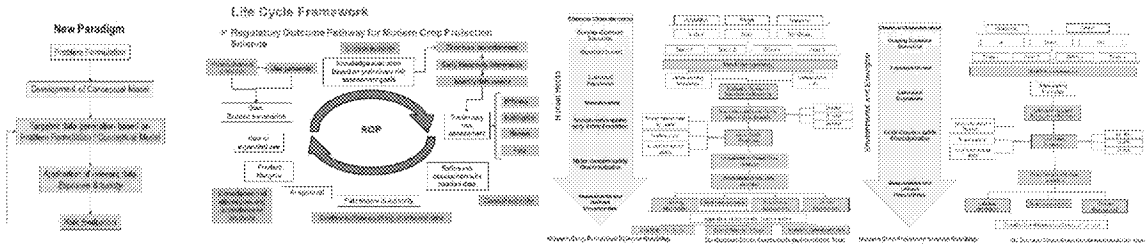
Lack of focus on science, the goal is off target, ID the lists of hazards rather than scientifically defensible risk assessments on innovative solutions.

Hazard is the priority rather than exposure and risk. Lack of focus on risk management.

Engagement with stakeholders and preliminary mind map of issues:



Conceptual Model:



Mapping the Approach:

Have already engaged US EPA, supportive of the concept and willing to invest staff time in helping to make this a success.

An AdvancingAgChem effort would bring together regulatory authorities and the regulated industry to discuss scientific and technical aspects of registration, would formally recognize the global aspect of the crop protection industry and encourage uniformity in testing requirements and most importantly how data are evaluated to support safe use and scientifically defensible human health and environmental risk assessment transcending mutual acceptance of data through a globally accepted framework for knowledge generation and evaluation to inform risk assessment.

New and developing technologies offer exciting opportunities to improve the current toxicity testing paradigms to provide better solutions and diminish animal testing as appropriate. Global data requirements prioritize "hazard" evaluation such that, in some regions, regulatory decisions bear very little relationship to plausible worst-case exposure scenarios following proper use of crop protection products. Risk assessment should be the basic operating principle for all regulatory decision-making, is essential to scientifically-defensible chemical product stewardship, and is the cornerstone for a successful and advanced AgChem industry.

The goals of such an effort would be:

To achieve harmonization in the interpretation and application of technical guidelines and requirements for product registration and the maintenance of registrations;

To provide a forum for constructive dialogue on scientific issues between regulatory authorities and the industry on the harmonization of the technical requirements and their evaluation for products;

To contribute to the global protection of public health and the environment in the interest of agriculture and the consumer;

To regularly update harmonized technical requirements and their evaluation leading to a greater mutual acceptance of data;

To avoid divergent requirements as a result of scientific advances, development of new technologies, and their unequal global availability and understanding;

To facilitate the adoption of new or improved technical research and development approaches which update or replace current practices;

And to encourage the implementation and integration of common standards of evaluation and risk assessment through the dissemination and communication of information about and provision of training on, harmonized guidelines and their use.