Globally Harmonized System of Classification and Labeling of Chemicals (GHS) PPDC Meeting, May 3, 2017, Session 4f

Overview

An Office of Pesticide Programs (OPP) workgroup is exploring options to require the use of GHS language on U.S. pesticide labels. OPP is requesting feedback on next steps and/or concerns from PPDC on this initiative before determining a path forward.

Background

GHS is a global initiative to promote standard criteria for classifying and communicating chemical hazards on chemical labels and Safety Data Sheets (SDS). This includes product identifiers, precautionary statements, pictograms, and signal words for physical, health, and environmental hazards. Currently, EPA has its own classification and labeling system that pre-dates GHS, which was adopted by the United Nations in 2003.

An Office of Pesticide Programs (OPP) workgroup is exploring potential options for requiring the use of GHS language on U.S. pesticide labels for relevant physical hazards and acute toxicity hazards only. OPP is not considering chronic health hazards that would add additional label requirements, or environmental hazards (GHS covers aquatic hazards only). This would support U.S. and international regulatory harmonization efforts and accelerate OPP's ability to utilize integrated approaches to testing and assessment (IATA).

Benefits of GHS Implementation for EPA & Stakeholders

GHS implementation would increase regulatory coordination across the federal government.

- In the U.S., the Occupational Safety and Health Administration (OSHA) and Department of Transportation (DOT) have updated their respective regulations to incorporate GHS.
- Currently, the EPA-regulated pesticide label and corresponding OSHA-regulated SDS can offer inconsistent hazard information for pesticide products. PR Notice 2012-1 provides guidance on conformance between OSHA and EPA labeling requirements, but inconsistencies remain.
- In 2016, the EPA Office of Land and Emergency Management (OLEM) and the Office of Pollution Prevention and Toxics (OPPT) both updated or proposed updates to relevant regulations to align with OSHA's GHS-aligned Hazard Communication Standard (HCS).
- Similarly, the 2015 EPA updates to the Worker Protection Standard included changes to be consistent with OSHA standards where possible (respirator fit testing, medical evaluation, and training) to provide chemical handlers and first responders consistent information.

GHS implementation would reduce non-tariff related barriers to trade. Harmonization across hazard labeling internationally would reduce the time and financial burden associated with regulatory compliance in a global economy.

• Many countries have fully implemented GHS. As of 2015, European Union countries and Turkey have implemented GHS for all chemical substances and mixtures, including pesticides.

- Other countries are currently implementing GHS. Brazil began GHS implementation in 2011 and is in the process of implementing it for pesticides. Thailand and Vietnam have begun GHS implementation with completion set for 2020 and 2018, respectively. In Australia, agricultural and veterinary chemicals are partially exempted from GHS labeling requirements.
- Canada and Mexico are currently implementing GHS for workplace chemicals. The transition
 period ends in May and October of 2018. Canada's Pest Management Regulatory Agency
 (PMRA) is already reporting GHS categories in their science reviews for acute toxicity studies.

GHS facilitates the use of alternative testing methodologies, tools that will enhance the quality of risk assessment and risk management decisions with significant reductions in animal testing.

- OECD is only developing new test guidelines using the GHS categories. Without GHS, EPA must develop cross-walks between the category systems across all the toxicities to utilize the data under EPA's regulatory framework. Adoption of the GHS categories would eliminate this barrier and accelerate incorporation of alternative approaches.
- GHS is testing- and test method-neutral, meaning no new data would be required with this
 change. All acceptable data previously submitted to EPA will not be actively re-evaluated as
 part of this effort.

Considerations

Rulemaking and the subsequent review of all product labels would require significant program resources, and result in corresponding time and cost burdens for industry and state co-regulators during the implementation phase.

- Extensive internal and external outreach and training would also be needed, as well as integration with ongoing program efforts such as SmartLabel. The transition period would likely be several years after a final rule was published.
- A complete cost-benefit assessment would be conducted as part of the rulemaking process. However, OPP is currently conducting cursory reviews of assessments from other agencies and countries to make inferences for both internal and external stakeholders.

Previous attempts to explore GHS implementation have been met with resistance from stakeholders.

- Changing EPA's hazard categories and subsequent labeling requirements would require rulemaking that would include many opportunities for public input throughout the process.
- In more recent years, OPP stakeholders have been engaged and highly supportive of OPP's work toward adoption of non-animal test methods and IATA. GHS implementation was identified as a possible solution to barriers to adopting alternative test methods as a result of these collaborative efforts.
- Additionally, GHS has since become more widely adopted in the U.S and abroad, but states may also have concerns regarding trickle down impacts on state requirements and resources.

Next Steps

The workgroup will continue raising stakeholder awareness and seeking stakeholder input on this potential initiative throughout Fiscal Year 2017.