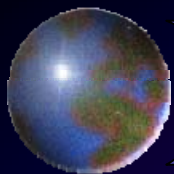


Globally Harmonized System of Classification and Labelling of Chemicals (GHS): Update

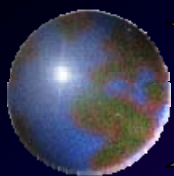
Mary Frances Lowe
U.S. Environmental Protection Agency
Pesticide Program Dialogue Committee
Washington, DC

May 11-12, 2005



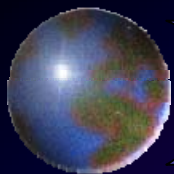
What is the GHS?

- ❖ A common and coherent approach to defining and classifying hazards, and communicating information on labels and safety data sheets.
- ❖ Target audiences include workers, consumers, transport workers, and emergency responders.
- ❖ Underlying infrastructure for establishment of national, comprehensive chemical safety programs.



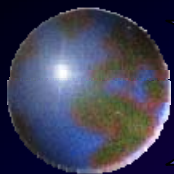
Scope of the GHS

- Harmonization of major existing systems for chemicals in transport, in the workplace, pesticides and consumer products—without lowering the level of protection
- Classification based on intrinsic properties/hazards
- Scope covers all chemicals
- Consistent with U.S. regulatory framework



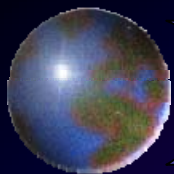
GHS Goals

- ❖ To promote safer transport, handling and use of chemicals world wide
- ❖ To facilitate international trade in chemical products by promoting greater consistency in regulatory requirements
- ❖ To reduce need for testing and evaluation
- ❖ To assist countries in developing strategies for sound management of chemicals



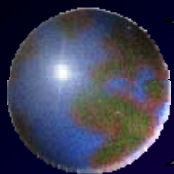
How was the GHS developed?

- ✿ UNCED 1992 mandate
- ✿ Decade of tripartite, consensus negotiations (government and stakeholder representatives)
- ✿ Three focal points: physical hazards, health and environmental hazards, and hazard communication
- ✿ Coordinating Group chaired by U.S.



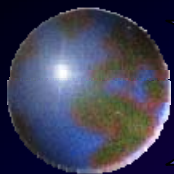
What are the implications of GHS for EPA programs?

- ➊ Implementation would affect all pesticide labels
- ➋ Every pesticide user and handler would need to understand the new labels
- ➌ Other regulations and policies related to classification categories need review



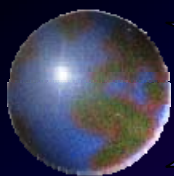
What should be harmonized (currently regulated by EPA)

- Classification criteria for physical hazards, health hazards, and aquatic toxicity, for substances and mixtures
- Certain standardized label elements: hazard pictograms, signal words, and hazard statements
- [Product and supplier identifiers, precautionary statements]



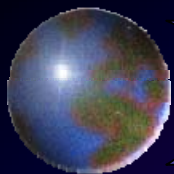
What does not need to change to be consistent with GHS (also important to EPA)

- Supplemental information
- Testing methods and data requirements
- Scope of hazards covered (building block approach)
- Downstream effects



To Implement the GHS: Basic Principles

- Cover all pesticides alike (some will be unclassified)
- Adopt GHS for all hazard classes for which we now label
- In general, limit changes to those required for GHS consistency



General Comparison of GHS and OPP Classification and Labeling and Policies

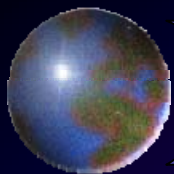
- Effects/hazard classes covered
- Test methods and requirements, basis of classification, e.g., for mixtures
- Symbols/pictograms
- Signal words: health, environmental, physical hazards
- Hazard statements

Hazard Classes on Labeling (“Building blocks”)

Hazard class	GHS	OPP
Acute toxicity (lethality)	Yes	Yes
Skin corrosion/ Irritation	Yes	Yes
Serious eye damage/ Irritation	Yes	Yes
Respiratory or skin sensitization	Yes	Skin only
Germ cell mutagenicity	Yes	No

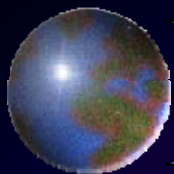
Hazard Classes on Labeling (“Building blocks”) - 2

Hazard class	GHS	OPP
Carcinogenicity	Yes	No
Reproductive toxicity	Yes	No
TOST/single Exposure	Yes	Methanol, Others?
TOST/ repeat exposure	Yes	No
Aquatic toxicity	Yes	Yes -acute only



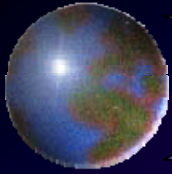
Flammability & Physical Hazards

- Recommend adopt all GHS classes and label elements
- Includes test methods for physical hazards
- Adopt GHS signal words (**NEW**) and other label elements



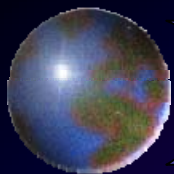
Product Identifier

- Current product and chemical names and registration number requirements satisfy GHS provisions
- Ingredient disclosure rules differ for inerts, but GHS provides that CBI rules may override ingredient disclosure provisions
- No changes in CBI policies with GHS



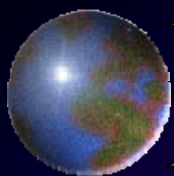
General Implementation Expectations

- Voluntary international system—no binding treaty obligations on countries
- To extent that countries adopt GHS into their systems, binding regulatory changes for industry
- Intent is that countries with systems will adapt them to be consistent with the GHS, and
- Countries that do not have systems will adopt GHS as their basic system
- Timing: international goal of 2008



Benefits to U.S. Stakeholders

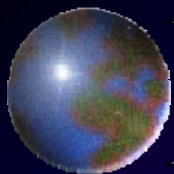
- Greater consistency in information provided to people exposed to chemicals
 - *increase health and environmental protection by providing clear, consistent label messages to users of chemicals, workers and the public*
 - *signal words, pictograms, and hazard statements will have the same meaning in all settings/across sectors and internationally*



Benefits to U.S. Stakeholders (2)

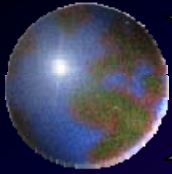
- ➊ Greater consistency in regulatory requirements U.S. industry must meet, at home and abroad
 - *reduce market barriers and facilitate compliance by eliminating need to learn and comply with multiple hazard classification and communications systems*
 - *companies only have to classify once for all authorities that implement the GHS, including other domestic agencies*

Strategies to minimize the cost of label changes and permit smooth transition will be critical



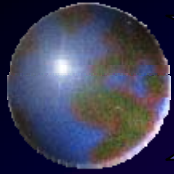
Key Issues for Consideration in EPA White Paper

- Scope of application
- Options for label submission and review:
separate approval process v. “routine
business” model
- Work-sharing possibilities? Pilot?
- Timing
- Effective outreach and education strategies



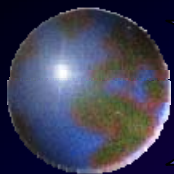
Comments received

- 1 Federal Agency
- 3 State and local government entities
- 7 Trade Associations
- 6 Individual registrant companies
- 2 Professional/educational associations
- 1 Consumer/public interest group
- 1 Individual expert
- Coalition of animal welfare/rights groups



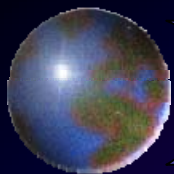
Issues in comments

- Cost/benefit considerations
- Technical/interpretation questions and issues requiring clarification (e.g., to avoid incentives for additional testing)
- Pros and cons of implementation options
- Education/training/enforcement issues
- Scope of coverage issues
- Interagency and international coordination issues



Next Steps

- ⊕ Work with stakeholders to address concerns, continued outreach and awareness-raising
- ⊕ Planning all-stakeholder meeting
- ⊕ Interagency coordinating process
- ⊕ Coordination with NAFTA and OECD pesticides groups
- ⊕ Consideration of newer elements of the GHS (e.g., aspiration hazards) and work at the global level to avoid “moving target”



For more information:

- *For EPA White Paper, comparison document, Q's & A's:*

<http://www.epa.gov/oppfead1/international/globalharmon.htm>

- *For comments: EPA Docket OPP-2004-0205 at*

<http://docket.epa.gov/edkpub/do/EDKStaffCollectionDetailView?objectId=0b0007d4802cc6e6> (or, quick search "globally" in edocket)

Other questions?

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